



Cancer Prevention and Research Institute of Texas

Oversight Committee

Nominations Subcommittee Meeting

May 13, 2014

Basic Cancer Research Panel 1  
Tom Curran, Ph.D./FRS, Chair

Peer Review Panel Members for Approval

1. Allan Balmain, Ph.D.
2. Steve Fiering, Ph.D.
3. Jacquelyn Hank, Ph.D.
4. Frank Rauscher, Ph.D.
5. Heide Schatten, Ph.D.
6. Joshua Schiffman, M.D.
7. Bart Williams, Ph.D.
8. Yu-Ching Yang, Ph.D.

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## BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2.  
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

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NAME Balmain, Allan	POSITION TITLE Professor in Residence		
eRA COMMONS USER NAME (credential, e.g., agency login) abalmain			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	MM/YY	FIELD OF STUDY
University of Glasgow	BSc	1966	Hons. Chemistry
University of Glasgow	PhD	1969	Organic Chemistry
German Cancer Research Centre, Heidelberg, West Germany	Postdoctoral	1971-72	
University of Strasbourg, France	Postdoctoral	1969-71	

### A. Personal Statement

The goal of our research is to identify the genetic events that underlie multistage epithelial tumor development, using mouse models of cancer. We have focused on models that recapitulate the genetic heterogeneity in human populations, with a view to development of approaches to personalized diagnosis and treatment. The models used have primarily been focused on skin, but also include comparative analyses of lung carcinomas and lymphoma. The focus of the most recent projects is the development of "Systems Genetics" approaches to analysis of multistage carcinogenesis. These seek to integrate multidimensional data sets to provide a network view of normal genetic architecture in mouse and human tissues, and the perturbations that take place during development of benign tumors and their progression to metastasis. Studies to date have revealed important roles for genes and pathways linked to stem cell fate decisions, cell cycle control, and inflammation. These gene expression network approaches represent a novel and highly promising route to the identification of the critical interacting components of important cancer signaling pathways.

### B. Professional Experience

1972-1976 Tenured member of staff, German Cancer Research Centre, Heidelberg, Germany  
1976-1982 Staff Scientist, Beatson Institute for Cancer Research, Glasgow  
1982-1994 Group Leader, Beatson Institute for Cancer Research, Glasgow  
1984-1994 CRC Special Appointment  
1994-1996 Director of Laboratory Research, Professor of Molecular Oncology, University of Glasgow,  
Jerry Turner Fellow of the Cancer Research Campaign  
1996-1999 Vice President, Research, Onyx Pharmaceuticals, Richmond CA  
1999-2001 Professor of Cancer Genetics, Cancer Research Institute and  
Department of Biochemistry and Biophysics, University of California-San Francisco  
2001-present: Barbara Bass Bakar Distinguished Professor of Cancer Genetics, UCSF Helen Diller Family  
Comprehensive Cancer Center  
Co-Leader, UCSF Cancer Genetics Program. Director, Genome Analysis Core

### Honors

1970 Royal Society European Programme Fellowship  
1971 Alexander Von Humboldt-Stiftung Fellowship  
1991 Keynote Lecture, UK MBCN, Warwick  
1992 Distinguished Lecturer Series, Yale University  
1993 Keynote Lecture, ECCO 7 London  
1995 Fellow of the Royal Society of Edinburgh  
1999 UICC Roll of Honor  
2000 Tom Connors Prize and Lecture, British Association for Cancer Research

- 2003 Distinguished Lecturer Series, Harvard University School of Public Health  
 2004 Distinguished Visitor, Biomedical Research Council, Singapore  
 2004 The DiMaggio Lecture, Dana Farber Cancer Center  
 2006 Opening lecture, AACR conference on Cancer Susceptibility and Cancer Susceptibility Syndromes, Hawaii  
 2007 The Cori Award Lecture, Roswell Park, Buffalo, NY  
 2007 Keynote Address, CCRI, University of Texas, San Antonio, TX  
 2007 John B. Little Award, Harvard School of Public Health  
 2008 Keynote lecture, McArdle Cancer Center Symposium  
 2008 Keynote Lecture, European Symposium on Hormones and Cell Regulation Mont Ste Odile, France  
 2009 Keynote Lecture and J.Walter Juckett Distinguished Lecture, Vermont Cancer Center  
 2010 Keynote Lecture, 56<sup>th</sup> Annual Radiation Research Society Symposium, Hawaii  
 2010 Keynote Lecture, University of Maastricht Genetics Meeting, Maastricht  
 2011 American Skin Association Achievement Award  
 2013 Herman Beerman Award, Society for Investigative Dermatology  
 2013 Elected Fellow of the American Academy of Arts and Sciences.

### C. Selected Peer-reviewed Publications (from last 10 years).

1. To MD, Perez-Losada J, Mao J-H, Hsu J, Jacks T, **Balmain A**. A functional switch from lung cancer resistance to susceptibility at the *Pas1* locus in *Kras2<sup>LA2</sup>* mice. **Nature Genetics**. 2006 Aug;38(8):926-30.
2. Wakabayashi Y, Mao, JH, Brown K, Girardi M and **Balmain A**. Promotion of Hras-induced squamous carcinomas by a polymorphic variant of the Patched gene in FVB mice. **Nature**. 2007 Feb 15;445(7129):761-5.
3. Mao JH, Wu D; Perez-Losada J, Jiang T, Li Q; Neve RM, Gray JW, Cai WW, **Balmain A**. Crosstalk between Aurora-A and p53: frequent deletion or downregulation of Aurora-A in tumors from p53 null mice. **Cancer Cell**. 2007 Feb;11(2):161-73.
4. To MD, Wong CE, Karnezis AN, Del Rosario R, Di Lauro R, and **Balmain A**. *Kras* regulatory elements and exon 4A determine mutation specificity in lung cancer, **Nature Genetics**. 2008 Oct;40(10):1240-4.
5. Mao JH, Kim IJ, Wu D, Climent J, Kang HC, DelRosario R, **Balmain A**. FBXW7 targets mTOR for degradation and cooperates with PTEN in tumor suppression. **Science**. 2008 Sep 12;321(5895):1499-502.
6. Quigley DA, To MD, Pérez-Losada J, Pelorosso FG, Mao JH, Nagase H, Ginzinger DG, and Balmain A. Genetic architecture of mouse skin inflammation and tumor susceptibility. **Nature**. 2009 Mar 26;458(7237):505-8.
7. Quigley DA, To MD, Kim IJ, Lin, K, Albertson DG, Sjolund J, Pérez-Losada J and **Balmain A**. Network analysis of skin tumor progression identifies a rewired genetic architecture affecting inflammation and tumor susceptibility. **Genome Biology** 2011, 12:R
8. Wang YV, Leblanc M, Fox N, Mao JH, Tinkum KL, Krummel K, Engle D, Piwnica-Worms D, Piwnica-Worms H, **Balmain A**, Kaushansky K, Wahl GM. Fine-tuning p53 activity through C-terminal modification significantly contributes to HSC homeostasis and mouse radiosensitivity. **Genes Dev**. 2011 Jul 1;25(13):1426-38
9. Mao JH, Wu D, Kim IJ, Kang HC, Wei G, Climent J, Kumar A, Pelorosso FG, Delrosario R, Huang EJ, **Balmain A**. Hipk2 cooperates with p53 to suppress  $\gamma$ -ray radiation-induced mouse thymic lymphoma. **Oncogene**. 2011 Jul 25. doi: 10.1038/onc.2011.306.
10. To MD, Quigley DA, Mao JH, Del Rosario R, Hsu J, Hodgson G, Jacks T, **Balmain A**. Progressive Genomic Instability in the FVB/*KrasLA2* Mouse Model of Lung Cancer. **Mol Cancer Res**. 2011 Sep 20.
11. To MD, Rosario, RD, Westcott, PM, Banta KL, **Balmain A**. Interactions between wild type and mutant Ras genes in lung and skin carcinogenesis. **Oncogene**. 2012 Sep 3. doi: 10.1038/onc.2012.404
12. Kang, HC, Quigley DA, Kim IJ, Wakabayashi Y, Ferguson-Smith MA, D'Alessandro, M, Lane EB, Akhurst RJ, Goudie DR and **Balmain A**. Multiple Self-Healing Squamous Epithelioma (MSSE): rare

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## BIOGRAPHICAL SKETCH

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NAME Steven N. Fiering, Ph.D.	POSITION TITLE Associate Professor		
eRA COMMONS USER NAME SNFIERING			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	YEAR(s)	FIELD OF STUDY
University of Michigan, Ann Arbor	B.S.	1969-1975	Geology
Eastern Michigan University	M.S.	1983-1984	Microbiology
Stanford University	Ph.D.	1985-1990	Genetics
Fred Hutchinson Cancer Research Ctr., Seattle	Postdoc	1991-1997	Genetics

### A. Personal statement

I established the Dartmouth Transgenic and Genetic Construct Shared Resource upon my recruitment to Dartmouth in 1997 and have directed it since. In 2002 the Core C of the Immunology INBRE was funded as part of that grant and we have developed and provided genetically modified and experimentally manipulated mice under that grant ever since. The Immunology INBRE is in its third round of funding and we are focused on providing published immunologically relevant mouse models that are not currently available at Dartmouth. In that context we have established the ability to generate mice with humanized lymphocyte compartments and plan to continue to expand on that to include mice with myeloid as well as lymphoid humanization through hydrodynamic injection of human cytokine plasmids. We are enthused to collaborate with Dr. Berwin on developing these new models and providing them to him for experimental use.

### B. Positions and Honors

#### Employment / Experience

1975-1982 The Soy Plant, Ann Arbor, MI, Partner in a food processing business.  
9/82-12/84 Eastern Michigan University, Teaching Assistant, Microbiology  
9/85- 9/90 Graduate student in the laboratory of Dr. Len Herzenberg at Stanford  
10/90-9/91 Research Group Leader, AFRC Centre for Genome Research, Edinburgh, Scotland  
10/91-6/97 Postdoctoral Fellow in the lab of Dr. Mark Groudine, Fred Hutchinson Cancer Research Center  
6/97-7/04 Assistant Professor, Dept. of Microbiology/Immunology, Dartmouth Medical School  
7/01-7/04 Assistant Professor Genetics Department, Dartmouth Medical School  
7/04-7/12 Associate Professor, Depts. of Microbiology/Immunology & Genetics, Dartmouth Med School  
7/12- present Professor, Depts. Of Microbiology/Immunology and Genetics, Geisel School of Medicine at Dartmouth

#### Honors / Awards

1992-1995 NRSA postdoctoral fellowship;  
1995-1997 Scholars Award, American Society of Hematology;  
1995-2000 Burroughs-Wellcome Career Development Award

## BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.  
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Hank, Jacquelyn A		POSITION TITLE Research Professor	
eRA COMMONS USER NAME JAHANK			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	MM/YY	FIELD OF STUDY
University of Wisconsin, Madison	BS	05/74	Med. Microbiology
University of Wisconsin, Madison	MS	05/76	Med. Microbiology
University of Wisconsin, Madison	PhD	05/78	Med. Microbiology

### A. Personal Statements

As a UW Research Professor, I have led the efforts to evaluate blood specimens from patients receiving a variety of distinct forms of immunotherapies. These have included cell function, flow cytometry and ELISA assays for clinical trials (UW and cooperative group) testing gene therapies, vaccines, mAbs and cytokines. My experience will be of use to improve the monitoring of neuroblastoma patients receiving ch14.18 antibody and hu14.18-IL2 immunocytokine.

### B. Positions and Honors

#### Positions and Employment

1974-78	Predocotractor Trainee, Department of Medical Microbiology, University of Wisconsin-Madison, WI, Advisor: DW Smith
1978-80	Postdoctoral Fellow, Department of Immunobiology, University of Wisconsin-Madison, WI, Advisor: FH Bach, Project: Cloning of Alloreactive T Cells
1981-84	Project Associate, Cancer Research Institute Fellowship, Department of Human Oncology, University of Wisconsin-Madison, WI
1984-87	Assistant Scientist, Department of Human Oncology, University of Wisconsin-Madison, WI
1986-	Member, University of Wisconsin Comprehensive Cancer Center
1987-92	Associate Scientist, Department of Human Oncology, University of Wisconsin-Madison, WI
1992-03	Senior Scientist, Department of Human Oncology, University of Wisconsin-Madison, WI
2003-	Distinguished Scientist, Department of Human Oncology, University of Wisconsin-Madison, WI
2009-	Research Professor, Department of Human Oncology, University of Wisconsin-Madison, WI

### C. Selected peer-reviewed publications (in chronological order)

1. Sondel PM, Hank JA, Wendel T, Flynn B, Bozdech MJ. HLA identical leukemia cells and T cell growth factor activate cytotoxic T cell recognition of minor locus histocompatibility antigens in vitro. *J Clin Invest* 71:1779-86, 1983. PMID: PMC370383
2. Sosman JA, Kohler PC, Hank JA, Moore KH, Bechhofer R, Storer B, Sondel PM. Repetitive weekly cycles of recombinant human interleukin-2: responses of renal carcinoma with acceptable toxicity. *J Natl Cancer Inst* 80:60-3, 1988.
3. Hank JA, Robinson RR, Surfus J, Mueller BM, Reisfeld RA, Cheung NK, Sondel PM. Augmentation of antibody dependent cell mediated cytotoxicity following in vivo therapy with recombinant Interleukin-2. *Cancer Res* 50:5234-9, 1990.
4. Hank JA, Albertini MR, Schiller J, Sondel PM. Activation of multiple effector mechanisms to enhance tumor immunotherapy. *J Immunother Emphasis Tumor Immunol* 14:329-35, 1993.
5. Frost JD, Hank JA, Reaman GH, Friedrich S, Seeger RC, Gan J, Anderson PM, Ettinger LJ, Cairo MS, Blazar BR, Krallo M, Matthay KK, Reisfeld RA, Sondel PM. Phase I/IB trial of murine monoclonal anti-GD2 antibody 14.Ga plus interleukin-2 in children with refractory neuroblastoma: a report of the Children's Cancer Group. *Cancer* 80:317-33, 1997.
6. Hank JA, Surfus J, Gan J, Albertini M, Lindstrom M, Schiller JH, Hotton KM, Khorsand M, Sondel PM. Distinct clinical and laboratory activity of two recombinant interleukin-2 preparations. *Clin Cancer Res* 5:281-9, 1999.

7. Hank JA, Surfus JE, Gan J, Ostendorf A, Gillies SD, Sondel PM. Determination of peak serum levels and immune response to the humanized anti-ganglioside antibody interleukin-2 immunocytokine. *Methods Mol Med* 85:123-31, 2003.
8. King DM, Albertini MR, Schalch H, Hank JA, Gan J, Surfus J, Mahvi D, Schiller JH, Warner T, Kim K, Eickhoff J, Kendra K, Reisfeld R, Gillies SD, Sondel PM. A phase I clinical trial of the immunocytokine EMD 273063 in melanoma patients. *J Clin Oncol* 22:4463-73, 2004. PMID: PMC2367368
9. Osenga KL, Hank JA, Albertini MR, Gan J, Sternberg AG, Eickhoff J, Seeger RC, Matthay KK, Reynolds CP, Twist C, Krailo M, Adamson PC, Reisfeld RA, Gillies SD, Sondel PM. A phase I clinical trial of the hu14.18-IL2 (EMD 273063) as a treatment for children with refractory or recurrent neuroblastoma and melanoma: a study of the Children's Oncology Group. *Clin Cancer Res* 12:1750-9, 2006. PMID: PMC2587020]
10. Mahvi DM, Henry MB, Albertini MR, Weber S, Meredith K, Schalch H, Rakhmilevich A, Hank JA, Sondel PM. Intratumoral injection of IL-12 plasmid DNA: results of a phase I/IB clinical trial. *Cancer Gene Ther* 14:717-23, 2007.
11. Cassaday RD, Sondel PM, King DM, Macklin MD, Gan J, Warner TF, Zuleger CL, Bridges AJ, Schalch HG, Kim KM, Hank JA, Mahvi DM, Albertini MR. A phase I study of immunization using particle-mediated epidermal delivery of genes for gp100 and GM-CSF into uninvolved skin of melanoma patients. *Clin Cancer Res* 13:540-9, 2007.
12. Gilman AL, Ozkaynak MF, Matthay KK, Krailo M, Yu AL, Gan J, Sternberg A, Hank JA, Seeger R, Reaman GH, Sondel PM. Phase I study of ch14.18 with granulocyte-macrophage colony-stimulating factor and interleukin-2 in children with neuroblastoma after autologous bone marrow transplantation or stem-cell rescue: a report from the Children's Oncology Group. *J Clin Oncol* 27:85-91, 2009. PMID: PMC2645092
13. Hank JA, Gan J, Ryu H, Ostendorf A, Stauder MC, Sternberg A, Albertini MR, Lo KM, Gillies SD, Eickhoff J, Sondel PM. Immunogenicity of the Hu14.18-IL2 immunocytokine molecule in adults with melanoma and children with neuroblastoma. *Clin Cancer Res* 15:5923-30, 2009. PMID: PMC2745522
14. Shusterman S, London WB, Gillies SD, Hank JA, Voss SD, Seeger RC, Reynolds CP, Kimball J, Albertini MR, Wagner B, Gan J, Eickhoff J, DeSantes KB, Cohn SL, Hecht T, Gadbar B, Reisfeld RA, Maris JM, Sondel PM. Anti-tumor activity of hu14.18-IL2 in relapsed/refractory neuroblastoma patients: a Children's Oncology Group (COG) phase II study. *J Clin Oncol*, 2010. PMID: PMC3020698
15. Delgado DC, Hank JA, Kolesar J, Lorentzen DF, Gan J, Seo S, Kim K, Shusterman S, Gillies SD, Reisfeld RA, Yang R, Gadbar B, Desantes KB, London WB, Seeger RC, Maris JM, Sondel PM. Genotypes of NK cell KIR receptors, their ligands, and Fc gamma receptors in the response of neuroblastoma patient to Hu14.18-IL2 immunotherapy. *Cancer Res* 70:9554-61, 2010. PMID: PMC2999644

## BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.  
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME <b>RAUSCHER, Frank Joseph, III</b>		POSITION TITLE <b>Professor, Deputy Director, The Wistar Institute Cancer Center</b>	
eRA COMMONS USER NAME <b>FRAUSCHER</b>			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	MM/YY	FIELD OF STUDY
Moravian College, Bethlehem, PA	B.S.	05/79	Biology
Roswell Park Cancer Institute, SUNY-Buffalo, Dept. Pharmacology & Experimental Therapeutics, Buffalo, NY	Ph.D.	05/87	Molecular Pharmacology
Roche Institute of Molecular Biology, Nutley, NJ (Laboratory of Dr. Tom Curran)	Postdoc	05/87-04/90	Molecular Oncogenesis

### A. PERSONAL STATEMENT

Our Laboratory focuses on the molecular genetics of human cancer with particular emphasis on the structure-function aspects of tumor suppressor and oncogenic proteins, mechanisms of transcriptional regulation, transcriptional control of cellular differentiation programs, as well as organogenesis and epigenetic control of gene silencing. We use biochemical and structural biology, in addition to genetic and chemical biology approaches to answer fundamental questions about gene regulation and cancer. The targets have included analysis of the FOS and JUN oncogenes, functions of the WT1 gene that, when mutated, causes Wilms' Tumor; BAP1, a gene encoding an enzyme that helps regulate levels of BRCA1 and is involved in the development of breast and lung cancers, and the PAX3-FKHR oncogenic transcription factor which causes rhabdomyosarcoma in children. Recently, our laboratory has turned its focus to three mechanisms of tumor progression and metastasis: 1) the SNAIL and SLUG zinc-finger proteins mediate gene silencing required for the early stages of breast tumor progression/metastases involving loss of adhesion, mesenchymal transformation and organ invasion. 2) The BAP1 metastasis suppressor, which is mutated in uveal melanoma and mesothelioma. 3) The TERE1 tumor suppressor gene prostate and bladder cancer and its role in castrate resistant prostate cancer and cholesterol/endogenous androgen production. Our Laboratory's overall goal is to identify and validate new novel targets for cancer therapeutics and prevention.

### B. POSITIONS AND HONORS

#### Positions:

1992-2008 Founder and Chairman, The Gene Expression and Regulation Program, The Wistar Institute Cancer Center, Philadelphia, PA

1990-Present Assistant, Associate and Full Professor, The Wistar Institute, Philadelphia, PA

1990-Present Member, University of Pennsylvania, Cell and Molecular Biology Graduate Group, Philadelphia, PA

1990-Present Adjunct Assistant, Associate, Full Professor of Genetics, University of Pennsylvania School of Medicine, Philadelphia, PA

1999-Present Deputy Director, The Wistar Institute Cancer Center, Philadelphia, PA

#### Selected Honors:

Pew Scholar in the Biomedical Sciences  
The Wilson S. Stone Memorial Award, MD Anderson Cancer Center  
The David M. Kovitz Visiting Professorship Award, MD Anderson Cancer Center  
The William L. McGuire, M.D. Memorial Fellowship, The Susan G. Komen Breast Cancer Foundation  
The George Khoury Memorial Lecture, National Institutes of Health



Annual Esther Zoller Breast Cancer Lecture, University of California, San Francisco, CA  
The Edward Rotan Visiting Professorship, MD Anderson Cancer Center  
The Annual Elizabeth Weitzenhoffer Blass Lecture in Cancer Genetics, University of Arkansas

Selected Advisory/Peer Review Activities:

2000-2010	Editor-in-Chief, Cancer Research
1996-2002	Member, Integration Panel, DOD Breast Cancer Research Program
1995-1996	Susan G. Komen Breast Cancer Foundation Research, Project Grant Selection and Review Committee
1996-2005	Ad hoc member, NIH Study Sections MBY1, CDF-1, CBY-2, GM-B, NCI SEPs
1998-2003	Member, American Cancer Society Study Section: Genetic Mechanisms in Cancer (GMC)
2005-2008	Member, Board of Scientific Councilors-2, (BSC-2), NIH/NCI
2008-2010	Chairperson, Board of Scientific Councilors-2 (BSC-2), NIH/NCI
2008-Present	Member, Grants Working Group, California Institute for Regenerative Medicine (CIRM)

**C. PEER-REVIEWED PUBLICATIONS** (selected from total of 145)

1. Jensen DE, Proctor M, Marquis ST, Perry Gardner H, Ha SI, Chodosh LA, Ishov AM, Tommerup N, Vissing H, Sekido Y, Minna J, Borodovsky A, Schultz DC, Wilkinson KD, Maul GG, Barlev N, Berger SL, Prendergast GC, **Rauscher III FJ**. 1998. BAP1: a novel ubiquitin hydrolase which binds to the BRCA1 RING finger and enhances BRCA1-mediated cell growth suppression. *Oncogene* 16:1097-1112. PMID: 9528852.
2. Schultz DC, Friedman JR, **Rauscher III FJ**. 2001. Targeting Histone Deacetylase Complexes via KRAB-Zinc Finger Proteins: The PHD and Bromodomains of KAP-1 form a Cooperative Unit that Recruits a Novel Isoform of the Mi-2 $\alpha$  Subunit of NuRD. *Genes Dev* 15:428-443. PMCID: PMC312636.
3. Schultz DC, Ayyanathan K, Negorev D, Maul G, **Rauscher III FJ**. 2002. SETDB1: A Novel KAP-1 Associated histone H3, lysine-9-specific methyltransferase that contributes to HP1-mediated silencing of euchromatic genes by KRAB Zinc Finger Proteins. *Genes Dev* 16:919-932. PMCID: PMC152359.
4. Ayyanathan K, Lechner MS, Bell P, Maul GG, Schultz DC, Yamada Y, Tanaka K, Torigoe K, **Rauscher III FJ**. 2003. Regulated recruitment of HP1 to a euchromatic gene induces mitotically heritable, epigenetic gene silencing: a mammalian cell culture model of gene variegation. *Genes Dev* 17:1855-1869. PMCID: PMC196232.
5. Ayyanathan K, Peng H, Hou Z, Fredericks WJ, Goyal RK, Langer EM, Longmore GD, **Rauscher III FJ**. 2007. The AJUBA LIM Domain Protein is a Co-Repressor for SNAG Domain Medicated Repression and Participates in Nucleo-Cytoplasmic Shuttling. *Cancer Res* 67:9097-9106. PMID: 17909014.
6. Ivanov AV, Peng H, Yurchenko V, Yap KL, Negorev DG, Schultz DC, Psulkowski E, Fredericks WJ, White DE, Maul GG, Sadofsky MJ, Zhou MM, **Rauscher III, FJ**. 2007. PHD Domain-Mediated E3 Ligase Activity Directs Intramolecular Sumoylation of an Adjacent Bromodomain Required for Gene Silencing. *Mol Cell* 28:823-837. PMID: 18082607.
7. Langer EM, Feng Y, **Rauscher III FJ**, Kroll KL, Longmore GD. 2008. Ajuba LIM proteins are Snail corepressors required for neural crest development in Xenopus. *Dev Cell* 14:424-436. PMCID: PMC2279146.
8. Zeng L, Yap KL, Ivanov AV, Wang X, Mujtaba S, Plonikova O, **Rauscher III FJ**, Zhou MM. 2008. Structural Insights into the Functional Cooperativity of the Tandem PHD Finger-Bromodomain of human KAP1 in Sumoylation-Dependent Gene Silencing. *Nat Struct Biol* 15:626-633. PMCID: PMC3331790
9. Hou Z, Peng H, Ayyanathan K, Yan KP, Langer EM, Longmore GD, **Rauscher III FJ**. 2008. The LIM protein Ajuba recruits protein arginine methyltransferase 5 (PRMT5) to mediate SNAIL-dependent transcriptional repression. *Mol Cell Biol* 28:3198-3207. PMCID: PMC2423142.
10. Hou Z, Peng H, White DE, Negorev DG, Maul GG, Feng Y, Longmore GD, Waxman S, Zelent A, **Rauscher III FJ**. 2010. LIM protein Ajuba functions as a nuclear receptor co-repressor and negatively regulates retinoic acid signaling. *Proc Natl Acad Sci U S A* 107:2938-2943. PMCID: PMC2840334.
11. Fredericks WJ, McGarvey T, Wang H, Zheng Y, Fredericks NJ, Yin H, Wang LP, Hsiao W, Lee R, Weiss JS, Nickerson ML, Kruth HS, **Rauscher III FJ**, Malkowicz SB. 2013. The TERE1 (UBIAD1) bladder tumor suppressor protein interacts with mitochondrial TBL2: regulation of trans-membrane potential, oxidative stress and SXR signaling to the nucleus. *J Cell Biochem* 114:2170-2187. PMID: 23564352. PMC in Process.

**BIOGRAPHICAL SKETCH**

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.  
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME HEIDE SCHATTEN	POSITION TITLE PROFESSOR		
eRA COMMONS USER NAME SCHATTENH			
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)			
INSTITUTION AND LOCATION	DEGREE (if applicable)	YEAR(s)	FIELD OF STUDY
University of Heidelberg, Germany	Diploma	1974	Microbiology, Botany
Univ of Heidelberg, School of Music	Masters	1974	Music Edu, Violin
University of California, Berkeley	PredocFellow	1975	Cell&Reproductive Biology
University of Heidelberg, Germany	Ph.D.	1977	Cancer Biology
University of California, Berkeley	Postdoc	1977	Cell Biology

**A. Personal Statement**

My long-term research interests are focused on cell cycle regulation and on the role of the cytoskeleton during cell cycle progression and on abnormalities in cells affected by disease. My lab's specific interests include centrosomes (microtubule organizing centers; MTOCs), centrosome-microtubule interactions, and molecular abnormalities that play a role in aberrant cancer cell proliferation. We have previously shown that centrosome and cell cycle dysfunctions are implicated in the formation of abnormal mitoses that contribute to genomic instability with consequences for tissue heterogeneity. While working at the German Cancer Research Center in Heidelberg I have extensively studied anti-mitotic drugs to inhibit cancer cell proliferation including paclitaxel and griseofulvin, an anti-mitotic drug that has recently gained attention for its excellent potential to be developed as novel cancer drug for clinical applications.

I have served on several breast cancer study sections to provide expertise including cytoskeletal, cell cycle and signal transduction associated with cancer cell proliferation. I have entertained close interactions and collaborations with various colleagues at Cancer Research Centers as documented in several of my publications. I have also edited several books related to cancer including a new book titled "*The Centrosome: Cell and Molecular Mechanisms of Functions and Dysfunctions in Disease*" that has been published by Humana Press (Springer; July 2012) and contains 23 chapters by expert contributors with significant chapters dedicated to dysfunctions in breast cancer. In 2013, I have edited a book on "*Cell and Molecular Biology of Breast Cancer*" that contains 16 chapters written by experts in their respective area of expertise that has been published by Springer Science and Business Media, LLC. I have further edited a new book titled: "*Cell and Molecular Biology and Imaging of Stem Cells*" that is currently in production and contains several chapters on breast cancer stem cells and will be published in summer of 2014 by Wiley. I am currently editing a book on "*The Cytoskeleton: Cell and Molecular Mechanisms of Functions and Dysfunctions in Disease*" that will be published by Springer in 2014 and will include a number of chapters on cytoskeletal dysfunctions in breast cancer.

**B. Positions and Honors**Positions and Employment

1974-1977	Research Assistant, German Cancer Research Center, Heidelberg, Germany
1977-1981	Research Associate, Florida State University, Tallahassee, Florida
1981-1986	Associate Research Scientist, Adjunct Associate Professor, Florida State Univ, Tallahassee, FL
1984	UNESCO-ICRO Guest Professor, Cell and Devel. Biology, Palermo, Italy
1985/1986	Instructor in Embryology, Marine Biological Laboratories, Woods Hole
1989/1990	Instructor in Cell Biology, Hopkins Marine Station, Pacific Grove
1992	Visiting Scientist and Instructor, Centro de Investigacion DELIPN, Mexico City, Mexico
1992	Visiting Scientist, Inst. Cell Tumorbiol., German Cancer Center, Heidelberg
1993-1994	Research Associate Professor and Director of Electron Microscopy Facility, School of Dentistry, Dept. Oral Biology, Univ. of Alabama, Birmingham, AL
1986-1996	Senior Scientist in Cell Biology, Univ. Wisconsin-Madison, Madison, Wisconsin
1994-1996	Adjunct Assoc. Professor, Dept. Cell and Structural Biol. Univ. of Illinois at Urbana-Champaign

and Director, Center for Electron Microscopy  
 1996-1999 Assoc. Professor, Dept. Vet. Pathobiology and Director of Electron Microscopy Core Facility,  
 Univ. Missouri-Columbia, Columbia, Missouri  
 1996-2008 Associate Professor, Dept. Vet. Pathobiology, Univ. Missouri-Columbia  
 2008-present Professor, Department of Veterinary Pathobiology, Univ. Missouri-Columbia

#### Other Experience and Professional Membership, Honors and Awards

1993-1999; 2005-2007; 2010-2013 Member, Special NIH Study Sections on Shared Instrumentation  
 1994, 1998, 2001; 2009-2011 Member, Special NIH Study Sections on Small Business  
 1999-2002; 2005-2006 Member, NSF Study Sections on Instrumentation  
 2001-2010 Komen Breast Cancer Research Foundation Study Sections  
 2008-2011; 2012-2013 DOD Breast Cancer Research Study Sections  
 1986-1999 NASA Grant Awards  
 1996 Experimentation on Space Shuttle Endeavor  
 1998-2001 Cancer Research Center Support  
 1999-2001 NSF Award for Instrumentation  
 2000-present Editor for Biological Applications, *Microscopy and Microanalysis*  
 2003-present Editor, Reproductive Biology and Endocrinology  
 2001 DAAD- Visiting Scientist, Dept. Anaesthes. Humboldt Univ. Berlin  
 2003-2009 NIH grant awards  
 1979-present American Society for Cell Biology (ASCB)  
 1982-present Microscopy Society of America (MSA)  
 1989-present American Society for the Advancement of Science (AAAS)  
 2007-2009 Director on Council, Microscopy Society of America  
 2011-present Editorial Board, Journal of Reproductive and Stem Cell Biotechnology  
 2011-present Editorial Board, Scientifica (Cell Biology)  
 2012-present Editor, BioMed Research International  
 2014-present Associate Editor, Human Reproduction

#### **C. Selected book chapters and peer-reviewed publications (selected from 220 publications)**

- Schatten, H.** (2014). The role of centrosomes in cancer stem cell functions. In: Cell and Molecular Biology and Imaging of Stem Cells. Edited by **Heide Schatten**, published by Wiley (in production; publication date: 2014)
- Schatten, H.** (2013). The impact of centrosome abnormalities on breast cancer development and progression with a focus on targeting centrosomes for breast cancer therapy. In: Cell and Molecular Biology of Breast Cancer. Edited by Heide Schatten, published by Springer Science and Business Media, LLC.
- Kazmierczak, R.A., Dino, A., Eisenstark, A., and **Schatten, H.** (2013). New breast cancer treatment considerations: a brief review of the use of genetically modified (attenuated) bacteria as therapy for advanced and metastatic breast cancer. In: Cell and Molecular Biology of Breast Cancer. Edited by Heide Schatten, published by Springer Science and Business Media, LLC.
- Miao, Y-L., Zhang, X., Zhao, J-G., Spate, L., Zhao, M-T., Murphy, C.N., Prather, R.S., Sun, Q-Y., and **Schatten, H.** (2012). Effects of griseofulvin on *in vitro* porcine oocyte maturation and embryo development. *Environ Mol Mutagen.* 53(7):561-6. doi: 10.1002/em.21717.
- Schatten, H.**, and Sun, Q-Y. (2011). The significant role of centrosomes in stem cell division and differentiation. *Microsc Microanal.* 17(4):506-512. Epub 2011 Jul 11.
- Lin, S-L., Yan, L-Y., Liang, X-W., Wang, Z-B., Wang, Z-Y., Qiao, J., **Schatten, H.**, and Sun, Q-Y. (2009). A novel variant of ER-  $\alpha$ , ER- $\alpha$ 36 mediates testosterone-stimulated ERK and Akt activation in endometrial cancer Hec1A cells. *Reprod. Biol. Endocrinol.* 7:102. doi:10.1186/1477-7827-7-102.
- Bukovsky, A., Aplin, J.D., Carson, R.J., Gaytán, F., Huleihel, M., Kruse, A., **Schatten, H.**, and Telleria, C.M. (2009). Immune physiology in tissue regeneration and aging, tumor growth, and regenerative medicine. *Aging* Vol. 1(2), 157-181.
- Schatten, H.** (2008). The mammalian centrosome and its functional significance. *Histo. Cell Biol.* 129:667-686.
- Gobert, G.N., Hueser, C.N., Curran, E., Sun, Q-Y, Glinsky, V. V., Welshons, W., Eisenstark, A., and **Schatten, H.** (2001). Immunolocalization of NuMA and phosphorylated proteins during the cell cycle in human breast and

## BIOGRAPHICAL SKETCH

NAME <b>Schiffman, Joshua D.</b>		POSITION TITLE Associate Professor	
EDUCATION/TRAINING			
INSTITUTION AND LOCATION	DEGREE	YEAR	FIELD OF STUDY
Brown University, Providence, RI	BS	1996	Psychology and Biology
Brown University, Providence, RI	MD	2000	Medicine
Stanford University, Palo Alto, CA	Internship	2001	Pediatrics
Stanford University, Palo Alto, CA	Residency	2003	Pediatrics
Stanford University, Palo Alto, CA	Chief Resident	2004	Pediatrics
Stanford University, Palo Alto, CA	Fellowship	2007	Pediatric Hematology and Oncology
University of Utah, Salt Lake City, UT	MS	2010	Clinical Investigation

### A. Personal Statement

I am a pediatric hematologist-oncologist with a clinical and research interest in the genomics of cancer and inherited cancer syndromes. Since arriving at the University of Utah in 2008, I have served as the Medical Director for the High Risk Pediatric Cancer Clinic at Huntsman Cancer Institute (HCI), where we evaluate children and families at high risk for cancer based on their personal and family medical histories. In addition, I run an independent translational genomics laboratory as a physician-scientist at HCI and have been actively involved in the research and discovery of genes related to familial cancers. The focus of my translational research is cancer susceptibility in families, with an emphasis on the genomic changes necessary for cancer development. Our lab is now pursuing copy number changes related to tumor development and functional assays related to risk of hereditary cancers. We also work closely with the Utah Population Database (UPDB) to understand both the medical and genetic risk factors associated with cancer development in children and their families. I serve as Education Director for the Program in Personalized Health Care, where I oversee the graduate and faculty seminars on applying personalized medicine to patient care. Using these resources, we recently discovered a genomic signature in Ewing sarcoma based on copy number alterations that predicts poor clinical outcome, and we're now pursuing further analysis of these candidate genes found within the copy number signature. All of these activities demonstrate my involvement in the genomics of cancer control and prevention, and highlight my research experience in the clinical and translational field of cancer genetics. I am dedicated to utilizing novel approaches and technologies to improve the value of healthcare delivered to patients at high risk for cancer development. This is especially important in the field of hereditary cancer and genomic medicine.

### B. Positions and Honors

#### Positions and Employment

2007-2008 Instructor, Stanford University, Division of Pediatric Hematology/Oncology, Stanford, CA  
 2007-2008 Co-Director, Pediatric Cancer Genetics Clinic (PCGC), Division of Pediatric Hematology/Oncology, Lucile Packard Children's Hospital, Stanford University, Stanford, CA  
 2008-2009 Visiting Instructor, Division of Pediatric Hematology/Oncology, Department of Pediatrics, University of Utah, Salt Lake City, UT  
 2008-present Medical Director, High Risk Pediatric Cancer Clinic, Huntsman Cancer Institute, University of Utah, Salt Lake City, UT  
 2008-present Member, Cancer Control & Population Sciences, Cancer Center Support Grant, Huntsman Cancer Institute, University of Utah, Salt Lake City, UT  
 2008-present Investigator, Huntsman Cancer Institute, University of Utah, Salt Lake City, UT  
 2009-2012 Assistant Professor, Division of Pediatric Hematology/Oncology, Department of Pediatrics, University of Utah, Salt Lake City, UT  
 2009-2012 Adjunct Assistant Professor, Department of Oncological Sciences, University of Utah, Salt Lake City, UT  
 2012-2013 Interim Director, Translational Oncology Core, Huntsman Cancer Institute, University of Utah, Salt Lake City, UT  
 2012- Associate Professor, Division of Pediatric Hematology/Oncology, Department of Pediatrics, University of Utah, Salt Lake City, UT

- 2012- Adjunct Associate Professor, Department of Oncological Sciences, University of Utah, Salt Lake City, UT
- 2012- Education Director, Program in Personalized Health Care, University of Utah, Salt Lake City, UT

### **Other Experience and Professional Memberships**

American Association for Cancer Research  
American Society of Clinical Oncology  
American Society of Hematology  
American Society of Pediatric Hematology/Oncology  
Children's Oncology Group  
Society for Pediatric Research  
American Society of Human Genetics

### **Honors**

- 2005 Dean's Postdoctoral Fellowship Grant, Stanford University, CA
- 2006 Fellow's Clinical Research Award, Society for Pediatric Research, Pediatric Academic Societies' Annual Meeting, San Francisco, CA
- 2006 The Walter V. and Idun Berry Fellowship Grant – Stanford University, CA
- 2007 The AACR-Aflac Scholar-in-Training Award, AACR Annual Meeting, San Diego, CA
- 2007 The Japanese Pediatric Society and Pediatric Academic Societies Fellow Exchange Award, Japanese Pediatric Society Annual Meeting, Kyoto, Japan
- 2008 Pediatric Research Fund-Children's Health Research Program Award for Early Career Investigators, Lucile Packard Foundation for Children's Health, Palo Alto, CA
- 2008 ASH Scholar Award (Clinical/Translational Research Fellow), American Society of Hematology Scholarship Foundation, Washington D.C
- 2008 Clinical-Translational Research Career Development Award in Pediatric Cancer, The Harriet H. Samuelsson Foundation, Oxnard, CA
- 2008 Hyundai Scholar Award – Hyundai Hope on Wheels Program, Fountain Valley, CA
- 2008 CureSearch Research Fellowship Award – Children's Oncology Group (COG), Bethesda, MD
- 2008 Primary Children's Medical Center (PCMC) Foundation/Pediatrics Innovative Research C Foundation, Salt Lake City, UT
- 2009 Pediatric Clinical and Translational (PCAT) Research Scholar, Department of Pediatrics, University of Utah, Salt Lake City, UT
- 2010 SARC Career Development Award - Sarcoma Alliance for Research through Collaboration, Ann Arbor, MI
- 2011 Children's Health Research Career Development Award (CHRCDA), Department of Pediatrics, University of Utah, Salt Lake City, UT
- 2011 Damon Runyon Cancer Foundation Clinical Investigator Award
- 2013 Wyss Family Visiting Professor in Pediatric Neuro-Oncology, Children's Hospital of Los Angeles, Los Angeles, CA
- 2013 Edward B. Clark, MD Endowed Chair in Pediatric Research, Department of Pediatrics, University of Utah, Salt Lake City, Utah

### **C. Selected Peer-Reviewed Publications (from over 60)**

1. **Schiffman JD**, Chun N, Fisher PG, Dahl GV, Ford JM, Eggerding FA. Identification of a novel p53 in-frame deletion in a Li-Fraumeni-like family. *Pediatr Blood Cancer*. 2008 Apr;50(4):914-916. doi: 10.1002/pbc.21247.
2. Hao HX, Khalimonchuk O, Schraders M, Dephoure N, Bayley JP, Kunst H, Devilee P, Cremers CW, **Schiffman JD**, Bentz BG, Gygi SP, Winge DR, Kremer H, Rutter J. SDH5, a gene required for flavination of succinate dehydrogenase, is mutated in paraganglioma. *Science*. 2009 Aug 28;325(5944):1139-1142. doi: 10.1126/science.1175689.
3. **Schiffman JD**, Wang Y, McPherson LA, Welch K, Zhang N, Davis R, Lacayo NJ, Dahl GV, Faham M, Ford JM, Ji HP. Molecular inversion probes reveal patterns of 9p21 deletion and copy number aberrations in childhood leukemia. *Cancer Genet Cytogenet*. 2009 Aug;193(1):9-18. doi: 10.1016/j.cancergencyto.2009.03.005 PMCID: PMC2776674.

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## BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors.  
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

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NAME Williams, Bart O.	POSITION TITLE Associate Professor and Director, VARI Center for Skeletal Disease Research		
eRA COMMONS USER NAME BARTWILLIAMS			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	YEAR(s)	FIELD OF STUDY
Carroll College, Waukesha, WI	B.S.	1991	Biology & Chemistry
MIT Center for Cancer Res., Cambridge, MA	Ph.D.	1996	Biology
National Cancer Institute, Bethesda, MD	Postdoctoral Fellow	1996-1999	Cancer Genetics / Cell Biology

### **Personal Statement**

My laboratory focuses on the generation and characterization of genetically engineered mouse models (GEMMs) to study the role of the Wnt signaling pathway in human disease. Our specific focus is the use of GEMMs to acquire insights into the mechanisms that underlie primary bone diseases such as osteoporosis and osteoarthritis and well as skeletal metastasis from breast and prostate tumors.

### **Positions:**

1991-1996 Graduate student – Dept. of Biology and Center for Cancer Research, MIT, Cambridge, MA  
1996-1999 Damon Runyon-Walter Winchell postdoctoral fellow – NCI, NIH, Bethesda, MD  
1999-2006 Scientific Investigator – Lab. of Cell Signaling and Carcinogenesis, Van Andel Research Institute, Grand Rapids, MI  
2006-2103 Senior Scientific Investigator (Associate Professor) – Lab. of Cell Signaling and Carcinogenesis, Van Andel Research Institute, Grand Rapids, MI  
2009-Date Director, Center for Skeletal Disease and Tumor Metastasis, Van Andel Research Institute, Grand Rapids, MI  
2013-Date Professor, Van Andel Research Institute, Grand Rapids, MI

### **Honors:**

1989 Undergraduate Research Grant Award, National Science Foundation  
1990 Delta Sigma Nu Scholastic Honor Society  
1990-1991 USA Today's All-USA Academic Third Team  
1991 Outstanding Senior Biology Student, Carroll College  
1996 Young Investigator Travel Grand Award, AACR Meeting, Lausanne, Switzerland  
1996-1999 Postdoctoral Fellowship Award, Damon Runyon-Walter Winchell Cancer Center Fund  
2004 Most Outstanding Abstract Award, ASBMR Annual Meeting

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## BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2.

Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

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NAME	POSITION TITLE		
eRA COMMONS USER NAME yuchungyang	Professor		
EDUCATION/TRAINING			
INSTITUTION AND LOCATION	DEGREE	MM/YY	FIELD OF STUDY
National Taiwan University, Taipei, Taiwan	BS	1975	Botany
National Taiwan University, Taipei, Taiwan	MS	1977	Biomedical Sciences
Northwestern University, Chicago, IL	PhD	1981	Microbiology- Immunology
NCI, NIH, Bethesda, MD	Postdoc	1984	Virology

### A. Personal Statement

My laboratory cloned Cited2 [CBP/p300-interacting transactivators with glutamic acid (E) and aspartic acid (D)-rich tail 2] as a cytokine inducible gene, generated total and conditional Cited2 knockout mice and characterized defects in different organs from embryonic or adult Cited2 knockout mice. We showed that Cited2 plays an important role in controlling quiescence of hematopoietic stem cells (HSCs) and this function is in part mediated through Hypoxia Inducible Factor (HIF)-1. We performed microarray analysis using long-term HSCs (LT-HSCs) isolated from wild type (WT) and Cited2 KO mice and identified several mitochondria related genes that are over-represented in both upregulated and downregulated gene pools affected by Cited2. We recently performed global metabolomic analysis using LT-HSCs isolated from WT and Cited2 KO mice, using highly sensitive GC/MS technology available at Metabolon and identified two major metabolic differences between WT and Cited2 KO HSCs: (1) branched-chain amino acid/Fatty acid (BCAA/FA) metabolism and (2) ROS. This RO1 intends to focus on BCAA/FA oxidation, which is under-explored mechanistically in HSCs.

I am currently a faculty in the Department of Biochemistry at Case, which has a long-standing tradition of studying metabolism with the past giants such as Dr. Harland Wood (discovered CO<sub>2</sub> fixation), Dr. Merton Utter [discovered pyruvate carboxylase and P-enolpyruvate carboxykinase (PEPCK)] and "Maestro of Metabolism" (by ASBMB), Dr. Richard Hanson (studied PEPCK "Mighty Mouse" and passed away on 02/28/2014). It is my intention that the current application will continue the rich history of studying metabolism in the Department. My research will benefit tremendously in collaboration with Dr. Chuck Hoppel through this application. Dr. Hoppel is an expert in fatty acid metabolism and mitochondrial diseases. Dr. Hoppel and I started our collaboration last year and published a JBC paper on how mouse ESCs balance energy demands and metabolism (glycolysis and oxidative phosphorylation) for cell fate decision. The current application represents a new direction for both Co-Pis: HSC biology is new to Dr. Hoppel and FA/BCAA is new for Dr. Yang. Our study in which we propose to study the role of Cited2/PML/PPAR in lipid and amino acid metabolism and HSC quiescence therefore explores an under-chartered area of research in hematopoiesis and has high significance in our basic understanding of HSC biology with translational potential in regenerative medicine and in treating blood diseases in general.

### B. Positions and Honors

#### Academic and Professional Experience:

1984-1985 Visiting Associate, Laboratory of Tumor Virus Biology, NCI, NIH, Bethesda, MD  
1985-1987 Staff Scientist, Genetics Institute, Cambridge, MA

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1987-1989 Principal Scientist, Genetics Institute, Cambridge, MA  
1989-1993 Associate Professor of Medicine and Biochemistry/Molecular Biology, Indiana University School of Medicine  
1993-2000 Professor of Medicine and Biochemistry/Molecular Biology, Indiana University School of Medicine  
2000-2007 Professor of Pharmacology, Case Western Reserve University School of Medicine  
2008-present Professor of Biochemistry, Case Western Reserve University School of Medicine

### **Honors:**

Leukemia Society of America Scholar Award (1991-1996)  
Leukemia Society of America Stohlman Memorial Scholar Award (1995-1996)  
Member of NIH Hematology-I Study Section (1993-1997); Hematopoiesis Study Section (2004-2008); NCI-F Manpower & Training Grants K99 and T32 (2011-2015)  
Editorial Board of Experimental Hematology (1994-1996)  
Editorial Board of Leukemia (1996-1998)  
Editorial Board of Blood (1998-2003)  
Editorial Board of JBC (2010-2015)  
Isador Jacob Goodman-Ruth Goodman Blum Professor in Cancer Research (2000-present)

### **Patents:**

U.S. 4,877,729: "Therapeutic uses of **IL-3**". Inventors: S.C. Clark, A.B. Ciarletta and Y-C. Yang.  
U.S. 5,414,071: "Human cytokine **Interleukin-9**", Inventors: Y-C. Yang, A.B. Ciarletta, S. Ricciardi and S.C. Clark.  
U.S. 5,371,193: "Mammalian cytokine, **IL-11**", Inventors: F. Bennett, S. Paul and Y-C. Yang.

### **Journal Reviewer:**

Journal of Immunology  
Blood  
Experimental Hematology  
Leukemia  
Oncogene  
Journal of Clinical Investigation  
Stem Cells  
Biochimica et Biophysica Acta  
Journal of Laboratory and Clinical Medicine  
Cytokine  
Journal of Leukocyte Biology  
Journal of Biological Chemistry  
American Journal of Pathology  
Clinical Cancer Research  
Gastroenterology  
Circulation Research  
Journal of Cellular Biochemistry  
PLoS ONE

### **Grant Reviewer:**

Ad Hoc for NIH Hematology-I Study Section (1992-1993 and 06/1998)  
NIH Study Section of the Special Emphasis Panel-K series review (03/1994 and 11/1994)  
NIH Small Business Innovative Research Special Study Section (07/1994 and 11/2003)

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External reviewer for Department of Veterans Affairs (04/1994, 04/1998 and 07/2007)  
Member of NIH Hematology-I Study Section (1993-1997)  
Ad Hoc for NIH Hematopoiesis Study Section (02/2004)  
Member of NIH Hematopoiesis Study Section (2004-2008)  
Site visit team for Laboratory of Experimental Immunology, NCI (11/1996)  
External reviewer for Nebraska State Initiative Grants (01/1998)  
External reviewer for National Central University (Taiwan) faculty promotion (11/1998)  
External reviewer for Department of Defense on breast cancer research (08/1999, 08/2000, 08/2001, 08/2002, 06/2003, 06/2009, 01/2010, 06/2010, 07/2010)  
External reviewer for The Wellcome Trust in UK (09/1999)  
Advisory Committee for the "National Science and Technology Program in Pharmaceuticals and Biotechnology", National Health Research Institutes, Taiwan (10/1999, 06/2000, 11/2001, 11/2002 and 08/2004)  
External reviewer for Department of Defense on ovarian cancer research (12/1999, 11/2000, 10/2001 and 04/2006)  
External reviewer for Department of Defense on prostate cancer research (07/2000, 08/2002, 04/2003, 06/2006, 04/2010, 07/2011)  
National Research Program for Genomic Medicine, National Science Council, Taiwan (03/2002 and 01/2005)  
Reviewer for American Cancer Society (Cuyahoga County Office) (2002-2007)  
Center Development Grant Review Panel for NHRI in Taiwan (09/2002 and 08/2004)  
Reviewer for Department of Defense Multidisciplinary Postdoctoral Award (03/2007)  
NCI-F Manpower & Training Grants K99 and T32 (09/2008, 10/2009, 09/2010 and 06/2011-06/2015)  
New York State Department of Health and the Empire State Stem Cell Board: Cell Cycle and Signalling panel (10/2008; 11/2009); Hematopoiesis (02/2012)  
NIH AED SEP (02/2009)  
NIH Hematopoietic Niche RFA (04/2009)  
NIH T32 SEP (10/2009)  
Fight for Sight grant review (01/2011)  
Member of NIH NCI-I Career Development Subcommittee (2012-2015)  
Member of Cancer Prevention Research Institute of Texas (CPRIT) Basic Cancer Research Scientific Peer Review Panel (2014-2017)

**C. Selected Peer-reviewed Publications** (selected from 109 peer-reviewed publications and 22 chapters/reviews)

Yin, Z., Haynie, J., Yang, X., Han, B., Kiatchosakun, S., Restivo, J., Yuan, S., Prabhakar, N.R., Herrup, K., Conlon, R.A. Hoit, B.D., Watanabe, M., and Yang, Y-C.: Essential role of Cited2, a negative regulator for HIF-1 $\alpha$ , in heart development and neurulation. Proc. Natl. Acad. Sci., USA, 99: 10488-10493,2002.

Chou, Y-T., Wang, H., Chen, Y., Danielpour, D., and Yang, Y-C.: Cited2 modulates TGF-b mediated up-regulation of MMP9. Oncogene, 25, 5547-60, 2006. Featured article for the issue.

Chou, Y-T., and Yang, Y-C.: Posttranscriptional control of Cited2 by TGF-b: regulation via Smads and Cited2 coding region. J. Biol. Chem. 281:18451-62, 2006.

Xu, B., Doughman, Y-Q., Turakhia, M., Jiang, W., Landsettle, C., Agani, F., Semenza, G.L., Watanabe, M., and Yang, Y-C. Partial rescue of defects in Cited2-deficient embryos by HIF-1a heterozygosity Dev. Biol. 301: 130-40, 2007.

Chen, Y., Haviernik P., Bunting, K.D., and Yang, Y-C.: Cited2 is required for normal hematopoiesis in the murine fetal liver. Blood, 110: 2889-98, 2007. Editorial on the article in the same issue.

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Basic Cancer Research Panel 2  
Carol Prives, Ph.D., Chair

Peer Review Panel Members for Approval

1. Nabeel Bardeesy, Ph.D.
2. Xinbin Chen, Ph.D., D.V.M.
3. James Manfredi, Ph.D.
4. Jeffrey Wrana, Ph.D.

## BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2. Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME <b>Nabeel Bardeesy, PhD</b>		POSITION TITLE Associate Professor of Medicine, Harvard Medical School; Associate Geneticist, Massachusetts General Hospital Cancer Center	
eRA COMMONS USER NAME (credential, e.g., agency login) <b>NBARDEESY</b>			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency if applicable.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	MM/YY	FIELD OF STUDY
McGill University, Montreal PQ, Canada	BSc	1991	Biochemistry
McGill University, Montreal PQ, Canada	PhD	1998	Biochemistry
Dana-Farber Cancer Inst., Harvard Medical School, Boston	Post-doc	1999-2005	Medical Oncology

### A. Personal Statement

The goals of my laboratory are to understand the molecular pathways underlying the pathogenesis of gastrointestinal malignancies, primarily pancreatic ductal adenocarcinomas and cholangiocarcinomas. Our studies focus on the convergence of cell metabolism and epigenetics in control overriding cellular differentiation programs and in enabling survival under cell stress states. Previously, my laboratory has generated a series of genetically engineered mouse models of gastrointestinal cancer, and used these models to study the key pathways driving tumorigenesis and controlling energy sensing. We elucidated the genetic interactions between oncogenic KRAS signaling and mutations in key tumor suppressors in pancreatic cancer progression. In additional work, we explored the link between the Lkb1 tumor suppressor and cell metabolism and tumorigenesis in multiple tissues. We have also uncovered key functions for the Mst1/Mst2 kinases and the mammalian Hippo pathway in organ size control, stem cell homeostasis and tumorigenesis. A major current focus is in understanding the mechanisms of cholangiocarcinoma development with a focus on the roles of IDH mutations in epigenetic and metabolic reprogramming in these cancers.

### B. Positions and Honors

#### Positions and Employment

9/1/91-9/1/98 PhD student, McGill University  
1/1/99-1/31/02 Postdoctoral Fellow, Dana-Farber Cancer Institute, Harvard Medical School, Supervisor: Ron DePinho  
2/1/02-3/31/05 Instructor in Medicine, Dana-Farber Cancer Institute, Harvard Medical School,  
4/1/05-4/1/12 Assistant Geneticist, Massachusetts General Hospital Cancer Center  
Assistant Professor of Medicine, Harvard Medical School  
4/1/12-present Associate Geneticist, Massachusetts General Hospital Cancer Center  
Associate Professor of Medicine, Harvard Medical School

#### Honors

1993-98 Medical Research Council of Canada Graduate Fellowship  
1999 Natural Sciences & Engineering Research Council Postdoctoral Award  
2000-02 American Cancer Society Fellowship: J.P Hoffman Award for Studies in Pancreatic Cancer  
2003-04 Lustgarten Foundation Award for Pancreatic Cancer Research  
2004-08 Forbeck Scholar Award  
2005-10 NCI K01 Howard Temin Award  
2008-09 Kimmel Scholar Award  
2008-09 AACR PanCAN Award  
2011 Harvard Medical School, Young Mentor Award  
2012 Gallagher Endowed Chair in Gastrointestinal Cancer Research

**BIOGRAPHICAL SKETCH**

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.  
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Chen, Xinbin	POSITION TITLE		
eRA COMMONS USER NAME CHENXIN	Professor of Comparative Oncology		
EDUCATION/TRAINING ( <i>Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.</i> )			
INSTITUTION AND LOCATION	DEGREE (if applicable)	YEAR(s)	FIELD OF STUDY
Anhui Agricultural University, China	B.S. (D.V.M.)	1982	Veterinary Medicine
Nanjing Agricultural University, China	M.S.	1985	Microbiology
Michigan State University, MI	Graduate Student	1985-1987	Animal Sciences
Michigan State University, MI	Ph.D.	1991	Microbiology

**A. Personal Statement**

For more than 20 years, my laboratory and I have worked on how p53 functions as a tumor suppressor. We have made a number of novel observations in delineating (1) how p53 functions as a sequence-specific transcription factor; (2) how p53 levels, functional domains and DNA damage determine the extent of the apoptotic response of tumor cells; (3) how p53 expression and activity are controlled in response to stress signals. In addition, we identified and characterized more than twenty target genes that mediate p53-dependent pro-survival and pro-death activities. Among these is RNPC1, also called Rbm38, which encodes a RNA-binding protein. Interestingly, we found that RNPC1 directly binds to p21 transcript and enhances p21 mRNA stability. Furthermore, we found that RNPC1 binds to p53 transcript and suppresses p53 mRNA translation. Thus, we identified p53-RNPC1 as a novel feedback loop in the p53 pathway.

**B. Positions and Honors**Postdoctoral Training

1981 - 1982: **Intern in Large Animal Veterinary Medicine**, Linbi County Veterinary Clinical Center, Anhui, China  
1992 - 1996: **Postdoctoral Fellow** at Dr. Prives Laboratory, Columbia University, New York

Academic Appointment

1996 to 2001: **Assistant Professor (1996-2001)**  
**Associate Professor (2001)** Medical College of Georgia, Augusta, Georgia  
2001 to 2007: **Associate Professor (2001-2004)**  
**Professor (2004-2007)** Departments of Cell Biology, University of Alabama at Birmingham  
**Co-Director (2003-2007)**, Tumor Biology Program, UAB Comprehensive Cancer Center  
March 2007 - **Professor**, Department of Surgical and Radiological Sciences, School of Veterinary Medicine; Department of Internal Medicine, School of Medicine, UC Davis  
**Director**, Comparative Cancer Center, UC Davis School of Veterinary Medicine  
**Director**, Veterinary Oncology Program, UC Davis School of Veterinary Medicine  
**Co-Leader**, Comparative Oncology Program at UC Davis Comprehensive Cancer Center

Honors and Awards

1. World Bank Graduate Student Fellowship, 1985 – 1987
2. American Cancer Society Postdoctoral Fellowship (declined), 1994
3. Department of Defense Breast Cancer Research Program Postdoctoral Fellowship, 1994 – 1997
4. DOD Breast Cancer Research Program Career Development Award, 1997 – 2001
5. Distinguished Teaching Award, School of Graduate Studies, Medical College of Georgia, 2000

6. Pfizer Distinguished Award for Research Excellence, School of Veterinary Medicine, UC Davis, 2010

#### Major Professional Activities

1. Scientific Editor, PLoS ONE, 2013 - 2015
2. Editor, BMC Molecular Biology, 2010 - 2014
3. Board Member, College of CSR Reviewers, National Institutes of Health, 2010 – 2012
4. Editorial Board Member, Journal of Biological Chemistry, 2007 – 2012
5. Editorial Board Member, Cancer Biology and Therapy, 2006 - present
6. Ad hoc reviewer for Mol. Cell. Biol., Science, Mol. Cell, Nature Genetics, Nature Cell Biology, Genes & Dev., EMBO J, EMBO Report, Oncogene, Cancer Res., Clinical Cancer Res., Mol. Cancer Res., NAR, J. Cell Science, Mol. Biol. Cell., J. Exp. Med., TIBS, J. Mol. Biol., Carcinogenesis, Mol. Carcinogenesis, Apoptosis, Cell Death and Differentiation, J. Virol., J. Cell. Biochem., Cell. Mol. Life Science, FASEB J., and J. Medical Genetics.

#### NIH Study Sections and Other Review Committees (selected since 2001)

1. NIH study sections - ad hoc member: MONC (June 2013, Oct. 2012, Feb. 2011, June 2010, October 2009, June 2009, Jan. 2009, Sept. 2008); CE (Oct. 2011, Feb. 2009, Feb. 2008); BMCT (Dec. 2013, May 2012, Feb. 2012, June 2011, Jan. 2007); CAMP (Jan. 2010); MG-B (Sept. 2011); CPA (June, 2001, Oct. 2001, Feb. 2002, June 2002, Oct. 2002, Jan. 2003, June 2003)
2. NIH Cancer Etiology study section - chartered member (Oct. 2003, Feb 2004, June 2004, Oct. 2004, Feb. 2005, June 2005, Oct. 2005, Feb. 2006, June 2006, Oct. 2006, Feb. 2007, June 2007)
3. NCI Special Panel (Nov. 2012, March 2013)
4. NIH/NCI PO1 program - ad hoc member: Molecular Oncology study section (Oct. 2003, May 2004, Feb. 2005, June 2005, Oct. 2009, March 2010, Jan. 2011); Translational Oncology study section (Oct. 2004, Feb. 2005, Oct. 2005, Jan. 2006, Oct. 2009)
5. NIH Special Emphasis Panels - ad hoc member: OBT-1 R15 (Sept. 2011), ZRG1 OBT-A (02) S (June 2011), MONC (Nov. 2010), TPM (Nov. 2003, Dec. 2009); Challenge grants (July 2009); CAMP (July 2009); Path B (June 2002, Oct. 2002, Nov. 2002, Feb. 2003, March 2003, July 2003, Nov. 2003); CPA (April 2003); AIDS and Related Research (July 2007)
6. Howard Hughes Medical Institute Fellowship Program - chartered member, 2012-2014
7. DOD Breast Cancer Research Program - ad hoc member, MBG1/3 (2001-2004, 2006-2008); Idea #1 (2008); Cell Biology Concept (2006-2009); Pathobiology (2004, 2005)
8. DOD Prostate Cancer Research Program - ad hoc member, MBG or Cell Biology (2008-2012); Cancer Therapeutics (2004); Exploration/Hypothesis Development (2006)
9. National Science Foundation - ad hoc member, April 2008
10. Florida Biomedical Research Program - Ad hoc reviewer, 2007-2012
11. Louisiana State University System Board of Regents Seed Grants - Ad hoc reviewer 2009
12. Taiwan National Science Council - Ad hoc reviewer, 2012
13. Australia National Health and Medical Research Council - Assessor, May 2009
14. United Kingdom Cancer Research Campaign – ad hoc member, Nov. 2008
15. American Federation for Aging Research, National Scientific Advisory Council, 2003, 2004, 2009
16. Philip Morris External Research Program Advisory Committee, 2003, 2004, 2007
17. Singapore National Science Foundation - ad hoc member, April 2006

#### **C. Publications relevant to the current application (selected from ~130 Peer-Reviewed Publications)**

1. Zhang M, Zhang J, Chen X, Cho SJ, Chen X. 2013. Glycogen synthase kinase 3 promotes p53 mRNA translation via phosphorylation of RNPC1. *Genes & Dev.* 27: 2246-2258.
2. Zhang Y, Yan W, Jung YS, **Chen X**. 2013. P63 regulates tubular formation via epithelial-to-mesenchymal transition. *Oncogene*, PMID: 23542170.
3. Cho SJ, Zhang J, Rossi A, Liu G, Zhang J, **Chen X**. 2013. Ninjurin1, a target of p53, regulates p53 expression and p53-dependent cell proliferation, premature senescence and radiation-induced mortality in vitro and in vivo. *Proc Natl Acad Sci.*, 110(23):9362-7. PMID: 23690620.

## BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors.  
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Manfredi, James, John		POSITION TITLE Professor of Oncological Sciences (with Tenure)	
eRA COMMONS USER NAME jamesjmanfredi			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	YEAR(s)	FIELD OF STUDY
Cornell University, Ithaca, NY	A.B.	1978	Biochemistry
Albert Einstein College of Medicine, Bronx, NY	M.S.	1981	Molecular Pharmacology
	Ph.D	1983	Molecular Pharmacology
Harvard University, Cambridge, MA	Post-doc	1983-1986	Cell Biology
Columbia University, New York, NY	Post-doc	1986-1989	Molecular Biology

### A. Personal Statement

My research interests have focused on the role of the tumor suppressor p53 and its pathway in mediating cellular responses to genotoxic stress with the goal of translating these findings into ways that can improve the efficacy of cancer therapy. p53 is known to mediate two predominant cellular responses, cell cycle arrest and apoptosis, but the molecular basis for this cell fate determination has remained elusive. The focus of the laboratory is in three main areas.

First, studies are focused on testing the hypothesis that an interplay between p53-independent effectors and p53-dependent gene expression may be the crucial determinant for cellular outcome. The optimal therapeutic response to DNA damage caused by many chemotherapeutic agents is cell death rather than inhibition of cell cycle progression. Elucidating the molecular mechanisms that are responsible for regulating the ability of p53 to trigger apoptosis versus arrest may lead to more effective therapeutic intervention and a way to overcome the chemotherapeutic-resistant phenotype found in many tumors.

Second, studies in the laboratory are addressing the role of p53 in mediating cell cycle arrest. The checkpoint in the G1 phase has been shown to be strictly p53-dependent. Due to the existence of a G2/M checkpoint that occurs in its absence, the precise role of p53 in preventing mitotic entry has been elusive. The significance of this research relates to the clinical implications of selective targeting of tumor cells with a defective p53 pathway, especially given the frequency of p53 mutation in cancer. Taken together, these studies will elaborate a detailed understanding of how p53 and its pathway mediate DNA damage checkpoints. This is expected to provide new avenues of pursuit that are relevant for prognosis and treatment of human cancer.

Third, the laboratory has been studying the role of the C-terminus of p53 in its tumor suppressor activity. Previous published studies demonstrated a role for the C-terminus in regulating target gene selection at both the level of sequence-specific DNA binding and co-activator recruitment (Resnick-Silverman et al. 1998; Hamard et al, 2012). Recently these studies have been extended in vivo. A mouse model has been generated that expresses an endogenous p53 that lacks the C-terminal 24 amino acids (Hamard et al., 2013). These mice show two overt phenotypes: a reduced number of hematopoietic stem cells leading to severe anemia and impaired proliferation of granule cells resulting in defective cerebellar development and ataxia. The underlying molecular basis involves tissue-specific alterations in p53 target gene selection and expression. These phenotypes were unexpected and have led me into areas of research that are entirely new for the laboratory and therefore quite exciting. These mutant mice are being studied to gain novel insights into the role of p53 in leukemia and medulloblastoma, as well as to provide new approaches for targeted therapies in these diseases. All told, I have worked in the p53 field for 28 years and have generated the expertise and reagents to successfully pursue these studies.

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## BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2.  
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

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NAME Jeffrey Wrana	POSITION TITLE
eRA COMMONS USER NAME (credential, e.g., agency login)	

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)

INSTITUTION AND LOCATION	DEGREE (if applicable)	MM/YY	FIELD OF STUDY
University of Toronto	B.Sc.	1980-1984	
University of Toronto	Ph.D.	1984-1991	Biochemistry

<u>Position</u>	<u>Location</u>	<u>Date</u>
Professor	Medical Genetics and Microbiology University of Toronto	2004-present
Senior Investigator	Program in Molecular Biology and Cancer SLRI, Mt. Sinai Hospital Toronto, Canada	1999-present
Senior Scientist	Program in Developmental Biology The Hospital for Sick Children Toronto, Canada	1999
Associate Professor	University of Toronto	1999-2004
Assistant Professor	University of Toronto	1996-1999
Research Scientist	Program in Developmental Biology The Hospital for Sick Children	1995-1999
Post-doctoral fellow	Cell Biology Program Memorial Sloan Kettering 1275 York Ave., NYC, NY, 10021	1991-1995
Ph.D.	Dept. of Biochemistry University of Toronto	1984-1991

### C. Professional Activities

#### Leadership

2002-present: Director of the Lunenfeld-Tanenbaum Research Institute High Throughput Biology Robotics (SMART) facility.

2007-2012: Development of Youth Outreach Program with support from the MRI-ORF to provide outstanding high school students with the opportunity to train over the summer in research science labs.

#### Committees

- Hospital for Sick Children Restracom Trainee Review Committee 1998-1999
- Hospital for Sick Children Internal Ad-Hoc Review Committees 1996-1999
- Credentials committee, Samuel Lunenfeld Research Institute (2000-present)
- Chair, Core Facility committee, Samuel Lunenfeld Research Institute (2002-present)
- Space committee, Samuel Lunenfeld Research Institute (2002-present)
- Toronto Western Hospital, Reg. Med. And Eye Research Search Committees (2002-2003)
- Dept. of Med. Genetics and Microbiology. Graduate Curriculum Committee (2003)
- Chair, SLRI Search Committee (2004)
- Toronto-McMaster Drug Discovery Pipeline Initiative; Working Group Committee (2004)
- Drug Development advisory committee; Ontario Institute for Cancer Research (2006-2007)
- MSH-MaRs commercialization committee (2006)
- SLRI Research Executive (2006- )

### **Consultant**

- Creative Biomolecules, Inc., Hopkinton, MA. (1997-2000); Ophidian Pharmaceuticals, Madison, WI. (1997-1998); Millenium Pharmaceuticals, Cambridge, MA. (1996); Signal Pharmaceuticals, San Diego, CA. (1998-2004); de Puy Orthopaedics Inc. (2001); Proctor and Gamble Pharmaceuticals. (2001); Genzyme (2004); Merck Pharmaceuticals (2005)

### **Grant and Award Review Panels**

- Panels: Israel Cancer Research Fund (1997-1999); National Cancer Institute of Canada, panel D (1998-1999); CIHR, Scholarship panel (2002); National Cancer Institute of Canada, Chair, Program Project Grant review committee (2002); Alberta Cancer Research Board (2003-2007)
- Chair, CFI-FRSQ review panel for Quebec; 2006 and 2008
- Ad hoc: Life Sciences Foundation, The Netherlands (SLW); Canadian Institutes of Health Research (CIHR); National Cancer Institute of Canada (NCIC); National Science and Engineering Research Council (NSERC); National Science Foundation, USA; North Carolina Biotechnology Center; Austrian Biomedical Research; PIRYA Awards committee, Ireland; Pfizer-FRSQ Awards Program (Quebec).
- Member Gairdner Medical Review Panel (2007-2011)
- Chair, Panel D; Canadian Cancer Research Society Research Institute (former NCIC) (2008-2011)
- Chair, Innovation Grants program, panel 1b; Canadian Cancer Research Society Research Institute (2012-)
- Member, SPARK Review Committee. Ontario Genomics Institute technology innovation funding program (2012)
- Member, Canadian Cancer Society Research Institute Impact Grant review panel (2014).



## **B. Positions and Honors**

### **Positions and Employment**

1983-1986	Postdoctoral Research Fellow, Department of Cellular and Developmental Biology Harvard University, Cambridge, MA (with Dr. Daniel Branton)
1986-1989	Postdoctoral Research Scientist, Department of Biological Sciences Columbia University, New York, NY (with Dr. Carol Prives)
1989-1993	Associate Research Scientist, Department of Biological Sciences Columbia University, New York, NY
1993-1996	Assistant Professor, Division of Neoplastic Diseases, Department of Medicine Mount Sinai School of Medicine, New York, NY
1995-2001	Assistant Professor, Department of Molecular, Cell, and Developmental Biology Mount Sinai School of Medicine, New York, NY
1997-2001	Assistant Professor, Derald H. Rittenberg Cancer Center Mount Sinai School of Medicine, New York, NY
2002-2006	Associate Professor, Department of Oncological Sciences (formerly designated Derald H. Rittenberg Cancer Center) Mount Sinai School of Medicine, New York, NY
2002-2006	Associate Professor, Department of Molecular, Cell, and Developmental Biology Mount Sinai School of Medicine, New York, NY
2007-2009	Associate Professor (with Tenure), Department of Oncological Sciences Mount Sinai School of Medicine, New York, NY
2007-2009	Associate Professor (with Tenure), Department of Developmental and Regenerative Biology (formerly designated Department of Molecular, Cell, and Developmental Biology) Mount Sinai School of Medicine, New York, NY
2010-present	Professor (with Tenure), Department of Oncological Sciences Mount Sinai School of Medicine, New York, NY
2010-present	Professor (with Tenure), Department of Developmental and Regenerative Biology Mount Sinai School of Medicine, New York, NY

### **Honors**

1981-1983	Pharmaceutical Manufacturers' Association Advanced Predoctoral Fellowship
1983-1985	Damon Runyon-Walter Winchell Cancer Fund Postdoctoral Fellowship
1985-1986	American Heart Association Postdoctoral Fellowship
1986	Certificate of Distinction in Teaching, Harvard-Danforth Center, Harvard University
1997-2001	Career Development Award, Department of Defense Breast Cancer Program
2006	Institute for Medical Education Teaching Award, Mount Sinai School of Medicine

### **Advisory Panels**

2002-2003	National Institutes of Health, CDF3 Study Section, Ad-hoc Member
2003-2008	National Institutes of Health, CAMP Study Section, Chartered Member
2009-2010	National Institutes of Health, CAMP Study Section, Ad-hoc Member
2010	National Institutes of Health, TCB Study Section, Ad-hoc Member
2005-2012	National Cancer Institute P01 Special Emphasis Panels, Ad-hoc Member
2009-2010	National Cancer Institute R13 Conferences Grants Panel, Ad-hoc Member
2010-2013	National Cancer Institute R13 Conferences Grants Panel, Chair
2012-2014	National Cancer Institute R03/R21 Panels, Ad-hoc Member
1998-2005, 2010, 2012	Department of Defense, Breast Cancer Program Review Panel, Member
2008-2010	Department of Defense, Breast Cancer Program Review Panel, Chair
1999-2000	Department of Defense, Ovarian Cancer Program, Review Panel, Member
2002-2004	Department of Defense, Prostate Cancer Program Review Panel, Member
2005-2008	Department of Defense, Prostate Cancer Program Review Panel, Chair
1997-1999, 2003-2005	California Breast Cancer Research Program Review Panel, Member
2000-2002, 2006-2009	California Tobacco-Related Diseases Program Review Panel, Member
2011-2012	California Tobacco-Related Diseases Program Review Panel, Chair
2012-2014	Molecular Cancer Research, Senior Editor

Cancer Biology  
Peter Jones, Ph.D., Chair

Peer Review Panel Members for Approval

1. John Carpten, Ph.D.
2. Yves De Clerck, M.D.
3. Napoleone Ferrara, M.D.
4. Geoffrey Wahl, Ph.D.

**BIOGRAPHICAL SKETCH**

Provide the following information for the key personnel and other significant contributors in the order

NAME <b>Carpten, John D.</b>	POSITION TITLE <b>Deputy Director of Basic Sciences and Professor</b>
eRA COMMONS USER NAME	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as*

INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	YEAR(s)	FIELD OF STUDY
Lane College, Jackson, TN	B.S.	1984-1988	Biology
The Ohio State University, Columbus, OH	Ph.D.	1988-1994	Molecular Genetics
National Human Genome Research Inst /NIH	Postdoc	1994-2000	Cancer Genetics

**A. Personal Statement**

My background includes graduate training at the Ohio State University with completion of the Ph.D. dissertation in 1994. Postdoctoral training was within the Cancer Genetics Branch at the National Human Genome Research Institute, NIH, Bethesda, MD with Dr. Jeffrey M. Trent and co-mentor Dr. Francis F. Collins. I was later promoted to the tenure track at NHGRI. Subsequently, I left to become a senior investigator and director for the Division of Integrated Cancer Genomics at the Translational Genomics Research Institute, Phoenix, AZ, where I now also serve as Deputy Director of Research. It is important to state that I have successfully mentored and trained over 20 students and fellows, several of whom have gone on to established careers in research and medicine. Furthermore, I have served as an external advisor on a number of NIH granted programs including P50 programs and NCI-designated comprehensive cancer centers. I have performed editorial duties for several major journals and am currently a Senior Editor for *Cancer Research*. I have been a permanent NIH study section member for both the National Cancer Institute and NHGRI, with ad hoc duties having been performed with NCRR and the DOD CDMRP prostate and breast cancer programs.

**B. Positions and Honors**

**Positions and Employment**

1994-2000 Research Fellow, National Human Genome Research Institute, NIH, Bethesda, MD

- 2000-2003 Investigator, Cancer Genetics, National Human Genome Research Institute, NIH, Bethesda, MD
- 2003-present Professor and Director, Division of Integrated Cancer Genomics, Translational Genomics Research Institute (TGen), Phoenix, AZ
- 2003-present Full Member, Arizona Cancer Center, University of Arizona, Tucson, AZ
- 2012-present Deputy Director of Basic Sciences, TGen, Phoenix, AZ

### **Honors**

- 2002 National Human Genome Research Institute Mentor Award
- 2003 National Medical Association Urology Section Achievement Award
- 2006 *Science Spectrum* Magazine, Trailblazer Award

### **C. Selected peer-reviewed publications (in chronological order from over >130).**

1. Huusko P, Ponciano-Jackson D, Wolf M, Kiefer JA, Azorsa DO, Tuzmen S, Weaver D, Robbins C, Moses T, Allinen M, Hautaniemi S, Chen Y, Elkahloun A, Basik M, Bova GS, Bubendorf L, Lugli A, Sauter G, Schleutker J, Ozcelik H, Elowe S, Pawson T, Trent JM, **Carpten JD**, Kallioniemi OP, Mousses S. Nonsense-mediated decay microarray analysis identifies mutations of EPHB2 in human prostate cancer. *Nature Genetics*. 2004 Sep; 36(9):979-83. Epub 2004 Aug 08.
2. Kittles RA, Boffoe-Bonnie A, Moses T, Robbins C, Ahaghotu C, Huusko P, Pettaway C, Vijayakumar S, Bennett J, Hoke G, Mason T, Weinrich S, Trent J, Collins F, Mousses S, Bailey-Wilson J, Furbert-Harris, Dunston G, Powell I, **Carpten JD**. A common nonsense mutation in EphB2 is associated with prostate cancer risk in African American men with a positive family history. *Journal of Medical Genetics*. 2005; 43(6):507-511. PMID: PMC2564535.
3. Baffoe-Bonnie AB, Kittles RA, Gillanders E, Ou L, George A, Robbins C, Ahaghotu C, Bennett J, Boykin W, Hoke G, Mason T, Pettaway C, Vijayakumar S, Weinrich S, Jones MP, Gildea D, Riedesel E, Albertus J, Moses T, Lockwood E, Klaric M, Faruque M, Royal C, Trent JM, Berg K, Collins FS, Furbert-Harris PM, Bailey-Wilson JE, Dunston GM, Powell I, **Carpten JD**. Genome-wide linkage of 77 families from the African American Hereditary Prostate Cancer study (AAHPC). *Prostate*. 2007; 67(1):22-31.
4. **Carpten JD**, Faber AL, Horn C, Donoho GP, Briggs SL, Robbins CM, Hostetter G, Boguslawski S, Moses TY, Savage S, Uhlik M, Lin A, Du J, Qian YW, Zeckner DJ, Tucker-Kellogg G, Touchman J, Patel K, Mousses S, Bittner M, Schevitz R, Lai MH, Blanchard KL, Thomas JE. A transforming mutation in the pleckstrin homology domain of AKT1 in cancer. *Nature*. 2007; 448(7152):439-444.
5. Tibes R, Kornblau SM, Qiu Y, Mousses SM, Robbins C, Moses T, **Carpten JD**. PI3K/AKT pathway activation in acute myeloid leukaemias is not associated with AKT1 pleckstrin homology domain mutation. *British Journal of Haematology*. 2008;140(3):344-347. PMID: PMC3385948

**BIOGRAPHICAL SKETCH**

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2.  
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Yves A. DeClerck, MD		POSITION TITLE Professor of Pediatrics and Biochemistry and Molecular Biology	
eRA COMMONS USER NAME (credential, e.g., agency login) DECLERCK			
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)			
INSTITUTION AND LOCATION	DEGREE (if applicable)	MM/YY	FIELD OF STUDY
Our Lady of Peace University, Namur, Belgium	BS	1966-July 1969	Medicine
Louvain University, Belgium	MD	1969-July 1973	Medicine
Louvain University, Belgium		1973-1975	Residency, Pediatrics
University of Montreal, Canada		1975-1977	Residency, Pediatrics
University of Southern California		1977-1979	Fellow, Ped Hem-Onc

**A. Personal Statement**

My laboratory has been interested in the study of the interactions between tumor cells and their micro-environment for more than 27 years of uninterrupted support from the NIH. The initial focus of our investigations was on the extracellular matrix and in particular on its degradation by matrix metalloproteinases (MMPs) and its role in tumor invasion. Over the last 10 years our research has extended to the investigation of the interactions between tumor cells and stromal cells and in particular mesenchymal cells and their role in bone metastasis in neuroblastoma. The work supported by this PPG led to the discovery of interactive pathways between neuroblastoma cells and mesenchymal stem cells in which inflammatory cytokines play a central role. My laboratory has published more than 120 scientific publications and reviews in this field, which have been quoted more than 6,000 times. My leadership in the area of the tumor microenvironment includes being the 2010-2011 elected chair of the AACR Tumor Microenvironment Working Group, a senior editor of *Cancer Research* for the microenvironment and immunology section, the co-chair of the NCI-Tumor Microenvironment Network 2014-2016 and the co-chair of several conferences on the microenvironment in cancer. I have been the co-leader of the TME program at the USC Norris Comprehensive Cancer Center since 1993. I have been involved as a program PI in the program project grant on the "Biology and Therapy of High Risk Neuroblastoma" since it was originally funded in 2000. Over the last 2 years I have closely worked with Dr. Seeger on progressively assuming the leadership of the overall program. As the past director of The Saban Research Institute at CHLA (1995 to 2010) and presently the PI of a U54 grant "Center for Environment-mediated Drug Resistance in Pediatric Cancer", I have significant experience in leading cooperative research projects.

**B. Positions and Honors****Positions and Employment**

1979	Clinical Instructor in Pediatrics, USC School of Medicine, Div of Hematology-Oncology, CHLA
1979-1980	Research Fellow, University of Liege, Belgium
1980-1981	Assistant Clinical Professor of Pediatrics, USC Sch of Medicine, Div of Hematol-Oncol, CHLA
1982-1988	Assistant Professor of Pediatrics, USC School of Medicine, Div of Hematol-Oncol, CHLA
1988-1994	Associate Professor of Pediatrics, USC School of Medicine, Div of Hematol-Oncol, CHLA
1991-1992	Visiting Scientist, International Institute of Cellular and Molecular Pathology, Catholic Univ Louvain Medical School, Brussels, Belgium
1993-Present	Program Leader, Tumor Microenvironment Program, Norris Comprehensive Cancer Ctr, USC
1994-Present	Professor of Pediatrics and Biochemistry & Molecular Biology, USC Keck School of Medicine
1995-2010	Vice President, Research, and Director, The Saban Research Institute of Childrens Hospital LA
1999-2000	Visiting Professor, Department of Anatomy, University of California, San Francisco
2007	Visiting Professor, International Institute of Cellular and Molecular Pathology, Catholic Univ Louvain Medical School, Brussels, Belgium

### **Honors**

S.P.E.C.I.A. Prize for Outstanding Medical Student, 1973  
American Cancer Society Junior Faculty Clinical Fellowship, 1982-1985  
Fogarty Senior International Fellowship, 1991-1992  
H. Russell Smith Award for Innovation in Pediatric Biomedical Research, 1991  
CHLA Associates and Affiliates Chair in Tumor Biology, 1994-present  
Richard Call Family Endowed Chair in Pediatric Research Innovation, 2010-present  
USC Associates Award for Creativity in Research, 2013

### **Consultant**

Editorial Board, *Cancer Research*, Associate Editor 1999-2001, 2003-2009  
Editorial Board, *Cancer Research*, Senior Editor 2010-present  
Editorial Board, *Clinical Cancer Research*, Member 2002-2009  
Editorial Board, *Journal of Cell Physiology*, Member 2002-present  
Editorial Board, *European Journal of Cancer*, Member 1995-2005  
Editorial Board, *Cancer Today*, Member 2013-present  
NIH ad hoc Review; 1990, 1991, 1994-1997, 1999, 2001-2013  
NIH-NCI: Scientific Review Group - Subcommittee C, Member 1996-1997  
NIH: Pathology B Study Section, Ad hoc Member 1998-2002  
NIH: Pathology B Study Section, Member 2002-2003  
NIH: Tumor Progression and Metastasis Study Section, Member 2003-2006  
European Commission "Combating Cancer", Reviewer, 2006, 2008  
NIH: Tumor Microenvironment Study Section, Ad hoc Member 2008-2009  
Italian Association for Cancer Research (AIRC): Grant Reviewer, 2009, 2010, 2013, 2014  
NIH: Tumor Microenvironment Study Section, Member 2010-2012  
Stand Up 2 Cancer: 2011 Selection Committee  
NIH/NCI: Ad hoc Member, Cancer Center Review, 2011-present  
Cancer Prevention Research Institute of Texas, Cancer Biology Scientific Review Panel, 2014  
Landon Foundation-AACR INNOVATOR Award for Research in Tumor Microenvironment Scientific Review Committee, 2014

### **Scientific Leadership**

American Assoc Cancer Research: Symposium on ECM, Proteases and Cancer, Oct. 9-13, 2002, Co-Chair  
American Assoc Cancer Research: Symposium on Cancer, Proteases, and the Tumor Microenvironment, Nov 30-Dec 4, 2005, Co-Chair  
American Assoc Cancer Research: Special Conference on Complexity of Tumor Microenvironments, Nov 3-6, 2011, Co-Chair  
American Association for Cancer Research: Scientist-Survivor Program, 2000, 2002, 2003, 2005, 2006, 2010-present  
American Assoc Cancer Research: Special Conferences Committee, 2005-2007  
American Assoc Cancer Research: Publications Committee, 2005-2012  
American Assoc Cancer Research: Tumor Microenvironment Working Group Steering Comm, 2007-2011  
American Assoc Cancer Research: Chairperson, Tumor Microenvironment Working Group, 2010-2011  
NIH: Co-Chair, NCI Tumor Microenvironment Network, 2011-2016

### **C. Selected Peer-reviewed Publications (selected from 120 peer-reviewed publications)**

#### **Most relevant publications related to this application**

1. Sohara, Y, Shimada, H, Scadeng, M, Pollack, H, Yamada, S, Ye, W, Reynolds, CP, and **DeClerck, YA**. Lytic bone lesions in human neuroblastoma xenograft involve osteoclast recruitment and are inhibited by bisphosphonate. *Cancer Res*, 63:3026-3031, 2003.
2. Sohara Y, Shimada H, Minkin C, Erdreich-Epstein A, Nolta JA and **DeClerck YA**. Bone marrow mesenchymal stem cells provide an alternate pathway of osteoclast activation and bone destruction by cancer cells. *Cancer Res*, 65:1129-1135, 2005.

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## BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.  
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

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NAME Napoleone Ferrara	POSITION TITLE Moores Cancer Center Senior Deputy Director, Division of Basic Science		
eRA COMMONS USER NAME (credential, e.g., agency login) NFERRARA			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	MM/YY	FIELD OF STUDY
University of Catania Medical School Catania, Italy	M.D.	04/81	Medical School

### A. Personal Statement

As the Senior Deputy Director for Basic Sciences at the Moores Cancer Center, the main research interests of my laboratory are the biology of angiogenesis and the identification of its regulators. Over twenty years ago my research team reported the isolation and cDNA cloning of vascular endothelial growth factor (VEGF) and proposed that this molecule plays a unique role in the regulation of angiogenesis. My laboratory focused on the investigation of the molecular and biological properties of VEGF. In 1993 we reported that inhibition of VEGF by specific monoclonal antibodies results in suppression of growth of a variety of tumors in vivo. These studies led to the development of a humanized anti-VEGF monoclonal antibody (bevacizumab) as a cancer therapy. Bevacizumab has been approved by the FDA for the treatment of several malignancies. Also, we reported that VEGF is an important mediator of angiogenesis associated with intraocular neovascular syndromes. These studies resulted in the clinical development of a humanized anti-VEGF Fab (ranibizumab), which has been approved by the FDA as therapy for neovascular age-related macular degeneration and retinal vein occlusion. We are presently investigating mechanisms of tumor angiogenesis alternative to VEGF, in particular the role of factors produced by myeloid cells and fibroblasts.

### B. Positions and Honors

#### Positions

1983-1985 Postdoctoral Research Fellow, Reproductive Endocrinology Center, UCSF.  
1985-1986 Intern, Dept. of Obstetrics and Gynecology, Oregon Health Sciences University.  
1986-1988 Postdoctoral Research Fellow, Cancer Research Institute, UCSF.  
1988-1993 Scientist, Dept. of Cardiovascular Research, Genentech, Inc.  
1993-1997 Senior Scientist, Dept. of Cardiovascular Research, Genentech, Inc.  
1997-2002 Staff Scientist, Dept. of Molecular Oncology, Genentech, Inc.  
2002-2012 Genentech Fellow, Genentech, Inc.  
2012 – Pres Distinguished Professor of Pathology  
2012 – Pres Distinguished Adjunct Professor of Ophthalmology  
2012 – Pres Senior Deputy Director for Basic Sciences UC San Diego Moores Cancer Center

#### Honors

2004 Discover Magazine Award.  
American-Italian Cancer Foundation Prize.  
Italian Assoc. for Research and Therapy of Eye Disorders (AIRCMO) Prize.

2005 AACR Bruce F. Cain Memorial Award.  
Lefoulon-Delalande Institut-de-France Scientific Prize.

2006 Elected Member. National Academy of Sciences, USA.  
Passano Foundation Research Award.  
General Motors Cancer Research Award.

- Society for Medicines Research Award.
- 2007 C. Chester Stock Award Lecture. Memorial Sloan-Kettering Cancer Center.  
ASCO Science of Oncology Award.  
Doctor *honoris causa*. University of Eastern Piedmont. Novara, Italy.
- 2008 Macula Society Arnall Patz Award.  
Dr. Bruce I. Terman Memorial Lecture. Albert Einstein College of Medicine.  
Michael A. O'Connor Award. Mayo Clinic Angiogenesis Symposium.
- 2009 Eminent Lecture Series. National Cancer Institute.  
NDDO Honorary Award Lecture. Amsterdam.  
Pezcoller Foundation-AACR International Award.
- 2010 Macula Society-Michaelson Symposium Award.  
Lasker-DeBaakey Clinical Medical Research Award.  
Jules Gonin Lecture. Retina Research Foundation.
- 2011 Dr. Paul Janssen Award for Biomedical Research.  
ARVO/AFER Special Recognition Award.
- 2012 Juvenile Diabetes Research Foundation Award.  
The Economist Innovation Award (Bioscience).
- 2013 Breakthrough Prize in Life Sciences  
Elected Fellow AACR Academy
- 2014 Priscilla White Lecturership. Joslin Diabetes Center.  
2014 Lasker Lecture. APSA Meeting.

#### Editorial Boards

**Board Member:** Angiogenesis; Cancer Research; Cancer Discovery; Cardiac and Vascular Regeneration; Endothelium; Frontiers in Molecular and Cellular Oncology; Journal of Cardiovascular Pathobiology; Journal of Clinical Investigation; Lymphatic Research and Biology; Science Translational Medicine; Vascular Cell.

**Editor-in-Chief:** Molecular Cancer Therapeutics.

#### **C. Publications (Selected from 310)**

- Shojaei, F, Wu, X, Baldwin, ME, Zhong, C, Malik, A, Shanz, S, Fuh, G, Gerber, HP, Ferrara, N. Tumor refractoriness to anti-VEGF treatment is mediated by CD11b+Gr1+ myeloid cells. **Nature Biotechnol.** 25, 911-920, 2007. PMID: 17664940
- Lee, S, Chen, TT, Jordan, M, Murdock, J, Desai, S, Ferrara, N, Nagy, A, Roos, KP, Iruela-Arispe, L. Autocrine VEGF signaling is required for vascular homeostasis. **Cell.** 130, 691-703, 2007. PMID: 17719546, PMCID: PMC3010851
- Shojaei, F, Wu, X, Zhong, C, Yu, L, Liang, XH, Yao, J, Blanchard, D, Peale, F, Bais, C, Van Bruggen, N, Ho, C, Ross, J, Tan, M, Carano R, Meng, YG, Ferrara, N. Bv8 regulates myeloid-cell-dependent tumour angiogenesis. **Nature.** 450, 825-831, 2007. PMID: 18064003
- Crawford, Y, Kasman, IM, Yu, L, Zhong, C, Wu, X, Modrusan, Z, Kaminker, J, Ferrara, N. PDGF-C mediates the angiogenic and tumorigenic properties of fibroblasts associated with tumors refractory to anti-VEGF treatment. **Cancer Cell.** 15, 21-34, 2009. PMID: 19111878
- Shojaei, F, Wu, X, Qu, X, Tan, M, Meng, G, Ferrara, N. G-CSF-initiated myeloid cell mobilization and angiogenesis mediate tumor refractoriness to anti-VEGF treatment in mouse models. **Proc. Natl. Acad. Sci. USA.** 106, 6742-6747, 2009. PMID: 19346489, PMCID: PMC2665197
- Chappel, JC, Taylor, SM, Ferrara, N, Bautch, VL. Local guidance of emerging vessel sprouts requires soluble Flt-1 (VEGFR-1). **Dev. Cell.** 17, 377-386, 2009. PMID: 19758562, PMCID: PMC2747120
- Lichtenberger, BM, Tan, PK, Niederleithner, H, Ferrara, N, Petzelbauer P, Sibilina, M. Autocrine VEGF signaling synergizes with EGFR in tumor cells to promote epithelial cancer development. **Cell.** 140, 268-279, 2010. PMID: 20141840
- Bais, C, Wu, X, Yao, J, Crawford, Y, McCutcheon, K, Tan, C, Yang, S, Vernes, JM, Easthan-Anderson, J, Haughney, P, Kowanetz, M, Hagenbeck T, Kasman, I, Meng, G, Hongo, JA, Stephan, JP, Shibuya, M, Ferrara, N. PlGF blockade does not inhibit angiogenesis during primary tumor growth. **Cell.** 141, 166-177, 2010. PMID: 20371352



**BIOGRAPHICAL SKETCH**

Provide the following information for the Senior/key personnel and other significant contributors.  
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Wahl, Geoffrey M.		POSITION TITLE Professor	
eRA COMMONS USER NAME (credential, e.g., agency login) GEOFFWAHL			
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)			
INSTITUTION AND LOCATION	DEGREE (if applicable)	MM/YY	FIELD OF STUDY
University of California, Los Angeles, CA Harvard University, Cambridge, MA Stanford University, Stanford, CA	B.A. Ph.D. Postdoctoral	06/70 06/76 1976-1979	Bacteriology Biological Chemistry Biochemistry

**A. Personal Statement**

I have been involved in various aspects of cancer research for my entire 40 year career in science, beginning with graduate school where I was a student with Dr. Mario Capecchi, and my postdoctoral fellowship with Dr. George Stark. Since that time, I have focused my efforts at identifying the molecules and mechanisms involved in the genetic and phenotypic diversity common to most human cancers. Thus, in the 1980's I studied the mechanisms of chromosome instability, typified by gene amplification. This work culminated in the discovery that chromosome breakage initiates the most common forms of structural chromosome changes in cancer cells. Equally important, these studies showed that such events do not happen at measurable rates in normal cells, and are likely initiated when cells enter S-phase under conditions that can lead to chromosome breakage. These findings led us to investigate the mechanisms that prevent instability from occurring in normal cells, and that are inactivated during cancer progression. This led to our identification of the p53 tumor suppressor as a key mediator of the DNA damage response that can prevent cells with irreparable or persistent damage from entering into S-phase, or continuing to cycle. Over the past 10 years we used cell culture and mouse genetic strategies to elucidate the mechanisms of p53 activation, and its roles in different cell types in vivo. We have more recently turned this knowledge of p53 activation mechanisms to the development of screening strategies to identify and isolate new types of small molecules that activate the p53 pathway in the 50% of cancers in which the gene is wild type. Finally, over the past four years, we have undertaken a new project related to breast cancer. Here, the objective is to determine when during embryogenesis stem cells committed to a mammary fate are formed, and whether these cells are the cells of origin of certain types of breast cancer.

Over my career, the diverse projects my lab has pursued required that we use or develop a broad range of techniques. My lab now has expertise with sophisticated in vitro cell culture systems enabling a vast array of genetic studies; we generate sophisticated mouse models to study cancer and do lineage tracing; we isolate rare stem cells by flow cytometry, and analyze them functionally by various types of transplantation; and we interrogate gene expression patterns in rare cell types, and use bioinformatics to deduce pathways central to stem cell identity, or that are involved in generating stem-like cells during cancer progression. I have mentored more than 50 graduate students/postdoctoral fellows during this time, and this has enabled me to develop successful mentoring skills to ensure that they receive the broad training necessary in all facets of planning and executing experiments, writing and criticizing manuscripts and grants, and orally presenting their results that they will require to conduct their independent scientific careers. Therefore, I have acquired all of the requisite experience and skills to conduct the proposed research, and should the situation arise where we need to implement a new approach or develop a new method to answer an important question, my publication record demonstrates my ability to either establish the appropriate collaborations with world-renowned specialists, or develop the technology needed, to overcome challenging or unexpected obstacles or to take advantage of new opportunities.

**B. Positions and Honors****Positions and Employment**

1975-1976 Research Assistant Professor, Biology Department, University of Utah, Salt Lake City, UT

1976-1979 Postdoctoral Fellow, Biochemistry Department, Stanford University, Stanford, CA  
1979-1984 Assistant Professor, The Salk Institute for Biological Studies, La Jolla, CA  
1984-1987 Associate Professor, The Salk Institute for Biological Studies, La Jolla, CA  
1985-1989 Adjunct Associate Professor, Biology Department, University of California, San Diego, CA  
1987-1989 Senior Member, The Salk Institute for Biological Studies, La Jolla, CA  
1989-present Professor, The Salk Institute for Biological Studies, La Jolla, CA  
1989-present Adjunct Professor, Biology Department, University of California, San Diego, CA

### **Professional Service**

2000-2002 External Advisory Board; University of California, San Diego Cancer Center  
2000-2003 Board of Directors; American Association for Cancer Research  
2000-2003 External Advisory Board; Roswell Park Memorial Institute  
2000-2003 Scientific Advisory Board; of the Keystone Symposia; Keystone, Colorado  
2002-present Editorial Board: DNA Repair, Molecular Cancer Research  
2002 Co-Chair: American Association for Cancer Research Intl. Meeting with Peter Jones  
2003 Co-Chair: American Association for Cancer Research Intl. Meeting with Ki Hong  
2004 Program Chair: American Association for Cancer Research Annual Meeting  
2005 President Elect: American Association for Cancer Research  
2005-2007 Board of Directors; American Association for Cancer Research  
2006-2007 President: American Association for Cancer Research  
2007-2008 Past President: American Association for Cancer Research  
2007-present Scientific Advisory Board of PanCAN  
2008-present TNCI Board Member (The Nicholas Connor Institute for Pediatric Cancer)  
2008-present M.D. Anderson Hospital, Scientific Advisory Board for Cancer Center  
2008-present Scientific Advisory Board on Cancer Stem Cells, MacroGenics, Inc.  
2010- Chair Elect: Salk Institute Faculty

### **Honors**

AAAS Fellow, Fellow of the AACR Academy, NIH Postdoctoral Fellowship; American Cancer Society Sr Fellowship; American Men and Women of Science; Award for Outstanding Contributions to Science Education, San Diego Science Educators' Association; "Citation Classic" Designation for One of the Most Highly Cited Scientific Papers, Senior Member of Sigma Xi

### **C. Selected Peer-reviewed Publications** (Selected from 160 peer-reviewed publications)

1. O'Gorman, S., Fox, D.T. and Wahl, G.M. (1991) Recombinase-Mediated Gene Activation and Site-Specific Integration in Mammalian Cells. *Science* 251:1351-1355.
2. Yin, Y., Tainsky, M.A., Bischoff, F.Z., Strong, L. C. and Wahl, G.M. (1992) Wild-type p53 Restores Cell Cycle Control And Inhibits Gene Amplification in Cells With Mutant p53 Alleles. *Cell* 70:937-948.
3. Di Leonardo, A., Linke, S.P., Clarkin, K., Wahl, G.M. (1994) DNA damage triggers a p53-dependent irreversible G1 arrest and prolonged induction of p21Cip1/WAF1/Sdi1/Pic1 in normal human fibroblasts. *Genes Dev* 8:2540-2551.
4. Aladjem, M., Groudine, M., Brody, L., Dieken, E., Fournier, R.E., Wahl, G.M., and Epner, E. (1995) Participation of the Human b-Globin Locus Control Region in Initiation of DNA Replication. *Science* 270:815-819.
5. Aladjem, M. I., Rodewald, L. W., Kolman, J. L., and Wahl, G. M. (1998) Genetic Dissection of a Mammalian Replicator in the Human b-Globin Locus. *Science* 281:1005-1009.
6. Jimenez, G.S., Nister, M., Beeche, M., Stommel, J.M., Barcarse, E., O'Gorman, S., and Wahl, G.M. (2000) A Transactivation-Deficient Mouse Model Provides Insights Into Trp53 Regulation and Function. *Nature Genetics* 26:37-43.
7. Stommel, J. and Wahl, G.M. (2004) Accelerated MDM2 Auto-Degradation Induced by DNA-Damage Kinases is Required for p53 Activation. *EMBO Journal*. 23:1547-1556.
8. Toledo, F., Krummel, K.A., Lee, C.J., Liu, C.W., Rodewald, L.W., Tang, M., Wahl, G.M. (2006) A mouse p53 mutant lacking the proline-rich domain rescues Mdm4 deficiency and provides insight into the Mdm2-Mdm4-p53 regulatory network. *Cancer Cell* 9(4):273-85
9. Wang, Y.V., Wade, M., Wong, E.T., Li, Y-C., Rodewald, L.W., and Wahl, G.M. (2007) Quantitative analyses reveal the importance of regulated Hdmx degradation for P53 activation. *Proc. Natl. Acad. Sci. USA* 104(30):12365-12370.
10. Wang, Y.V., Leblanc, M., Wade, M., Jochemsen, A.G., and Wahl, G.M. (2009) Increased radio-resistance and accelerated B-cell lymphomas in mice with Mdmx mutations that prevent modifications by DNA damage-activated kinases. *Cancer Cell* 16:33-43. PMID: PMC2758524

Cancer Prevention Research  
Thomas Sellers, Ph.D./M.P.H., Chair

Peer Review Panel Members for Approval

1. Fazlul Sarkar, Ph.D.
2. Chinthalapally Rao, Ph.D.

**BIOGRAPHICAL SKETCH**

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.

Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Sarkar, Fazlul		POSITION TITLE Professor	
eRA COMMONS USER NAME FSARKAR			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	YEAR(s)	FIELD OF STUDY
Calcutta University, India	BS	1971	Phys, Chem, Math
Aligarh Muslim University, India	MS	1974	Biochemistry
Banaras Hindu University, India	Ph.D.	1978	Biochemistry
Memorial Sloan Kettering Cancer Center, NY, USA	Post-Doc	1978-1982	Molecular Biology

A. Dr. Sarkar is a distinguished professor of pathology and oncology at Karmanos Cancer Institute, Wayne State University with a track-record of cancer research for more than three decades, and his broad research interest is focused on understanding the role of a “master” transcription factor, NF- $\kappa$ B and the regulation of its upstream and downstream signaling molecules in solid tumors especially focusing on breast, prostate, pancreas and colon cancer. Most importantly, the research focus of Dr. Sarkar has also been directed toward elucidating the molecular mechanism(s) of action of “natural agents” and synthetic small molecules for the prevention of tumor progression. He is one of the pioneers in developing natural agents such as Isoflavones, Curcumin and Indole compounds like DIM (B-DIM) for clinical use.. He has published over 400 original scientific articles in peer-reviewed journals and written more than 100 review articles and book chapters. He has been continuously funded by NCI, NIH and the Department of Defense (DOD) on several occasions. Dr. Sarkar has trained numerous pre-doctoral and post-doctoral students, and directed NIH funded research effectively. Dr. Sarkar’s current interest is focused on miRNAs in general but with particular attention to the role of miRNA in diabetes and pancreatic cancer. In addition, Dr. Sarkar served as a Senior Editor of the journal “Molecular Cancer Therapeutics” and he is a member of the editorial board of several cancer journals, and also served in many NIH and DOD study section panels over two decades.

**B. Positions and Honors.****Positions and Employment**

1982-1984 Research Associate, Interferon Laboratory, Sloan-Kettering Institute for Cancer Research, NY.

1984-1987 Assistant Researcher, Equivalent to Assistant Professor, Oakland University Rochester, MI, Worked on Steroid Hormones.

1987-1988 Director of Research, Oxford Biomedical Research, Inc., Rochester, MI. Worked on Carcinogens, mutagenesis and human cancer.

1988-1990 Director, Tumor Biology, Dept. of Pathology, Henry Ford Hospital, Detroit, MI. Worked on the Molecular Cell Biology of Human Tumors.

1990-1999 Associate Professor, Department of Pathology, Wayne State University School of Medicine, Detroit, MI. Worked on the Molecular mechanism of gene expression and regulation in human cancer development and progression.

1999-Present Professor, Department of Pathology, Wayne State University School of Medicine, Detroit, MI.

2011- Present Distinguished Professor, Department of Pathology and Oncology, Wayne State University School of Medicine

### **Other Experience and Professional Memberships**

Members of the American Association for Cancer Research, and American Society of Biochemistry and Molecular Biology.

### **Honors**

Member of NIH and DOD study sections

Member, Editorial Board of Journals

Academic Editor, PloS One

### **C. Selected peer-reviewed publications (in chronological order, relevant to current proposal )**

(Publications chosen from over 400 peer-reviewed publications)

1. Ahmad A, Sarkar SH, Bitar B, Ali S, Aboukameel A, Sethi S, Li Y, Bao B, Kong D, Banerjee S, Padhye SB, Sarkar FH. Garcinol regulates EMT and Wnt signaling pathways in vitro and in vivo, leading to anticancer activity against breast cancer cells. *Mol Cancer Ther* 2012;11:2193-201. PMC3836047
2. Ali S, Banerjee S, Logna F, Bao B, Philip PA, Korc M, Sarkar FH. Inactivation of Ink4a/Arf leads to deregulated expression of miRNAs in K-Ras transgenic mouse model of pancreatic cancer. *J Cell Physiol* 2012;227:3373-80. PMC3323695
3. Azmi AS, Mohammad RM, Sarkar FH. Can network pharmacology rescue nutraceutical cancer research? *Drug Discov Today* 2012;17:807-9.
4. Bao B, Ali S, Ahmad A, Azmi AS, Li Y, Banerjee S, Kong D, Sethi S, Aboukameel A, Padhye SB, Sarkar FH. Hypoxia-induced aggressiveness of pancreatic cancer cells is due to increased expression of VEGF, IL-6 and miR-21, which can be attenuated by CDF treatment. *PLoS One* 2012;7:e50165. PMC3521759
5. Bao B, Li Y, Ahmad A, Azmi AS, Bao G, Ali S, Banerjee S, Kong D, Sarkar FH. Targeting CSC-related miRNAs for cancer therapy by natural agents. *Curr Drug Targets* 2012;13:1858-68. PMC3792656
6. Kashat M, Azzouz L, Sarkar SH, Kong D, Li Y, Sarkar FH. Inactivation of AR and Notch-1 signaling by miR-34a attenuates prostate cancer aggressiveness. *Am J Transl Res* 2012;4:432-42. PMC3493023
7. Li Y, Maitah MY, Ahmad A, Kong D, Bao B, Sarkar FH. Targeting the Hedgehog signaling pathway for cancer therapy. *Expert Opin Ther Targets* 2012;16:49-66.
8. Roy S, Levi E, Majumdar AP, Sarkar FH. Expression of miR-34 is lost in colon cancer which can be re-expressed by a novel agent CDF. *J Hematol Oncol* 2012;5:58. PMC3464169
9. Soubani O, Ali AS, Logna F, Ali S, Philip PA, Sarkar FH. Re-expression of miR-200 by novel approaches regulates the expression of PTEN and MT1-MMP in pancreatic cancer. *Carcinogenesis* 2012;33:1563-71. PMC3499063
10. Tang J, Ahmad A, Sarkar FH. The Role of MicroRNAs in Breast Cancer Migration, Invasion and Metastasis. *Int J Mol Sci* 2012;13:13414-37. PMC3497334
11. Ahmad A, Maitah MY, Ginnebaugh KR, Li Y, Bao B, Gadgeel SM, Sarkar FH. Inhibition of Hedgehog signaling sensitizes NSCLC cells to standard therapies through modulation of EMT-regulating miRNAs. *J Hematol Oncol* 2013;6:77. PMC3852827
12. Li Y, Ahmad A, Kong D, Bao B, Sarkar FH. Recent progress on nutraceutical research in prostate cancer. *Cancer Metastasis Rev* 2013.
13. Roy S, Yu Y, Padhye SB, Sarkar FH, Majumdar AP. Difluorinated-curcumin (CDF) restores PTEN expression in colon cancer cells by down-regulating miR-21. *PLoS One* 2013;8:e68543. PMC3722247
14. Sethi S, Kong D, Land S, Dyson G, Sakr WA, Sarkar FH. Comprehensive molecular oncogenomic profiling and miRNA analysis of prostate cancer. *Am J Transl Res* 2013;5:200-11. PMC3612515
15. Yu Y, Sarkar FH, Majumdar AP. Down-regulation of miR-21 Induces Differentiation of Chemoresistant Colon Cancer Cells and Enhances Susceptibility to Therapeutic Regimens. *Transl Oncol* 2013;6:180-6. PMC3610548

## BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.  
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME: <b>Chinthalapally V. Rao</b>	POSITION TITLE: <b>Professor of Medicine</b>		
eRA COMMONS USER NAME: <b>chvrao</b>	<b>George Lynn Cross Research Professor</b>		
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	YEAR(s)	FIELD OF STUDY
Osmania University, Hyderabad, India	B.S.	1981	Biology & Chemistry
Osmania University, Hyderabad, India	M.S.	1983	Microbiology
Osmania University, Hyderabad, India	Ph.D.	1987	Microbiology
American Health Foundation-Cancer Center, Valhalla, NY	Post-doc/ Res. Assoc.	1988-90	Carcinogenesis/Nutrition/ Chemoprevention

### A. Personal Statement

Dr. Rao is an established leader in the field cancer chemopreventive drug development and nutritional carcinogenesis. His molecular targeted approaches in developing cancer chemopreventive drugs for colorectal, pancreatic and other epithelial cancer prevention/ treatment are nationally and internationally recognized. Several targeted drugs identified by Dr. Rao's research group in the preclinical models entered into the Phase II and III clinical trials conducted by the NCI, this includes COX-2 selective inhibitor, celecoxib and more recently low-dose combinational of statins and polyamine pathway inhibitors. In the field of targeted drug discovery, Dr. Rao is the first one to show that iNOS-, EGFR, ODC, and HMG-R select inhibitors as potential for colon and other epithelial cancers chemopreventive agents and greater efficacies when combined with low-doses agents with different mechanisms. Also, Dr. Rao's group is the first to show that combinational molecular targeting provides better synergistic efficacy without unwanted side effects. Dr. Rao led team of investigators in developing and optimizing animal models for understanding pathobiology of tumor progression and chemopreventive drug development. Recent years, Dr. Rao significant efforts in establishment pancreatic cancer research with emphasis on the early detection and preventive strategies. Dr. Rao's group optimized p48<sup>Cre</sup>. LSL-K-Ras<sup>G12D</sup> pancreatic ductal adenocarcinoma model for cancer prevention studies and shown several targeted prevent drugs usefulness for pancreatic cancer prevention. To better understand the relevance of transgenic mice models for human cancers we have recently completed whole transcriptome and miRNA sequencing using NGS-SoLID technology. In cancer genetics area, Dr. Rao has made important discoveries in elucidating putative role of BubR1 and Sgo1 in genetic instability and enhancement of colorectal and lung cancers. .

### B. Positions and Honors

#### Positions and Employment

- 1/91-12/94 Associate Research Scientist (Assistant Professor-tenure-track), Div. Nutrition and Chemoprevention, American Health Foundation Cancer Center (AHFCC), an NCI-designated cancer center, Valhalla, NY; Assistant Professor (Adj.), Dept. of Microbiology, New York Medical College, Valhalla, NY
- 1/95-4/98 Research Scientist (Associate Professor), Head, Chemoprevention Program, Div. Nutrition and Chemoprevention, AHFCC, Valhalla, NY. Associate Professor (Adj.), Dept. of Microbiology, New York Medical College, Valhalla, NY
- 5/98- 8/01. Scientist (Professor) & Associate Chief, Div. Nutritional Carcinogenesis, & Program co-Leader, Chemoprevention and Nutritional Carcinogenesis Program, AHFCC, Valhalla, NY.
- 9/01- 9/04. Chief, Div. Nutritional Carcinogenesis, and Program Leader, Chemoprevention and Nutritional Carcinogenesis Program, AHFCC, Valhalla, NY.
- 9/04- Pre. Professor and Kerley-Cade Endowed Chair in Cancer Research, Department of Medicine (Medical Oncology), Oklahoma Health Science Center, Oklahoma City, OK; Program Leader, Areodigestive Tract

- Cancers (9/2004 to 6/2006); Professor (2/05-Present, Graduate College; Department of Pathology; College of Pharmacy)
- 6/06-7/09. Chairman, Scientific Advisory Committee- & Program Leader, Cancer Chemoprevention, OU Cancer Center.
- 7/09-Pre. Director, Center for Cancer Prevention and Drug Development, PCS Oklahoma Cancer Center/OUHSC

### **Other Experience and Professional Memberships**

- *Member, NIH/NCI, Molecular Targets for Cancer Intervention (BMCT-C), 2012- Pr.*
- *Member, NIH, National Cancer Institute, Reviewer, Cancer Chemoprevention/Dietary Study Section (CDP) 2004-6/09.*
- *Member, NIH/NCI, Molecular Oncology and Cancer Prevention, Program Projects Grant Review Group, 2008-Pr.*
- *Member, NIH/NCI, Drug Discovery, Chemoprevention and Cancer Therapeutics-Program Projects Cluster (Basic and Preclinical) Review Group, 2004-pr.*
- *Member, NIH, National Cancer Institute, Reviewer, Cancer Biomarkers Study Section (CBSS) 2003-2004.*
- *Ad-hoc Member, NIH, National Cancer Institute, Reviewer, P30 Cancer Centers Program, 2006-2010*
- *Member, NIH/NCI, Cancer Disparities, Prevention and Prognostic Markers, Program Project Review Group, 2009-Pre.*
- *Member, NIH, National Cancer Institute, Reviewer, Metabolic Pathology Study Section (MP) 1998-2002)*
- *Consultant, Cancer Prevention, National Cancer Center, Tokyo, Japan. 2000-pre*

### **Honors**

- Young Scientist Award for Research Excellence from the Council of Scientific and Industrial Research, India, 1987
- The Princess Takamatsu Cancer Research Fellowship Award, Tokyo, Japan, 2002
- Kerley-Cash Cade Endowed Chair in Cancer Research, University of Oklahoma, 2004.
- Outstanding Achievement in Cancer Research from AACR- of American Asian Scientists in Cancer Research, 2007.
- Regents Award for “Superior Research and Creative Activity” from the Board of Regents of the University of Oklahoma, 2008.
- “George Lynn Cross Research Professor” from the Board of Regents and President - University of Oklahoma, 2011.

### **C. Peer-Reviewed Publications (Selected from 212) (Citations: >14,000; Article: >76; h-index: 44.7)**

#### **Most relevant articles for this proposal:**

1. **Rao, CV.**, Mohammed, A., Janakiram, N.B., Li, Q, Ritchie, R.L., Lightfoot, S, Awasthi, V., and Steele, V.E. (2012). Inhibition of Pancreatic Intraepithelial Neoplasia Progression to Carcinoma by Nitric Oxide-Releasing Aspirin in p48<sup>Cre</sup>.LSL-Kras<sup>G12D/+</sup> Mice. *Neoplasia*. 14(9) 778-787. **PMID: 23019409 (With Cover Page Illustration).**
2. Mohammed A, Janakiram NB, Brewer M, Ritchie RL, Marya A, Lightfoot S, Steele VE and **Rao CV** (2013). Anti-diabetes drug Metformin prevents progression of pancreatic cancer by targeting in part cancer stem cells and mTOR signaling. *Translational Oncol.*, 6:649–659. **PMID: 24466367 (With Cover Page Highlight)**
3. Mohammed A, Janakiram NB, Li Q, Madka V, Ely M, Lightfoot S, Crawford H, Steele VE, **Rao CV**. (2010) The epidermal growth factor receptor inhibitor gefitinib prevents the progression of pancreatic lesions to carcinoma in a conditional LSL-Kras<sup>G12D/+</sup> transgenic mouse model. *Cancer Prev Res*, Nov;3(11):1417-26. **PMID: 21084261 (Perceptive article emphasizing use transgenic models -future pancreatic preventive trials)**
4. Mohammed, A Janakiram, NB. Li .Q , Lightfoot, S., Steele, V.E. and **Rao, CV**. (2012). Atorvastatin delays progression of pancreatic lesions to carcinoma by regulating PI3/AKT signaling in p48<sup>Cre</sup>.LSL-Kras<sup>G12D/+</sup> mice. *Int. J Cancer*. 131 (8) 1951-1962; **PMID: 22287227 (With Cover Page Illustration).**
5. Mohammed, A., Janakiram, N.B., Gali, H, Lightfoot, S., Awasthi, V., and **Rao, CV**. (2012). Early Detection and Prevention of Pancreatic Cancer: Use of Genetically Engineered Mouse Models and advanced Imaging Technologies. *Current Medicinal Chemistry*;19 (12);3701-3713. **PMID: 22680929**
6. Mohammed, A Janakiram, NB. Brewer, M., Duff, A., Lightfoot, S., Brush, R.S., Anderson, R.E., and **Rao, CV**. (2012) Endogenous n-3 polyunsaturated fatty acids delay progress of pancreatic ductal adenocarcinoma in Fat-1.P48<sup>Cre</sup>.LSL-KRas<sup>G12D</sup> mice. *Neoplasia*, 14: 1249-1259. **PMID: 23308056**

Clinical and Translational Cancer Research  
Margaret Tempero, M.D., Chair

Peer Review Panel Members for Approval

1. Kathleen Cooney, M.D.
2. Fred Hirsch, M.D., Ph.D.
3. Albert Koong, M.D., Ph.D.
4. Ying Lu, Ph.D.
5. Pamela Munster, M.D.
6. Oliver Press, M.D., Ph.D.
7. Neil Shah, M.D., Ph.D.
8. Sarah Thayer, M.D., Ph.D.



## BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2.  
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Cooney, Kathleen A.	POSITION TITLE Frances and Victor Ginsberg Professor of Hem/Onc Professor of Internal Medicine and Urology Chief, Division of Hematology/Oncology		
eRA COMMONS USER NAME (credential, e.g., agency login) kcooney			
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)			
INSTITUTION AND LOCATION	DEGREE (if applicable)	MM/YY	FIELD OF STUDY
Dartmouth College, Hanover, NH	A.B.	1980	Biochemistry
University of Pennsylvania, Philadelphia, PA	M.D.	1984	Medicine
University of Michigan Med. Ctr., Ann Arbor, MI	Intern/Resident	1984-1987	Internal Medicine
University of Michigan Med. Ctr., Ann Arbor, MI	Chief Medical Resident	1987-1988	Internal Medicine
University of Michigan Med. Ctr., Ann Arbor, MI	Fellow	1988-1991	Hematology/Oncology

### A. Personal Statement

I am a medical oncologist with extensive experience in the clinical management of men with advanced prostate cancer. My research focuses on the genetic epidemiology of prostate cancer. I have been continuously funded by the NIH since 1995 for my research focused on understanding the molecular underpinnings of hereditary and familial prostate cancer. As the co-PI of the UM Prostate Cancer SPORE, I have also had the opportunity to participate in a number of clinical and translational prostate cancer research projects. I am also currently the Chief of the Division of Hematology/Oncology in the Department of Internal Medicine at the University of Michigan (U of M) and oversee the activities of 60 clinical faculty and 20 fellow.

### Positions and Honors

#### Positions and Employment

1991-1993	Lecturer/Research Fellow, Dept of Int Med, University of Michigan Med School, Ann Arbor, MI
1993-2000	Asst Professor, Dept of Int Med, University of Michigan Medical School, Ann Arbor, MI
1993-present	Physician, Medicine Service, Veteran's Affairs Medical Center, Ann Arbor, MI
1995-2000	Asst Professor, Dept of Surgery-Urology, Univ of Michigan Med School, Ann Arbor, MI
2000-2005	Assoc Professor (w/tenure), Depts of Int Med & Urology, U of M Medical School, Ann Arbor, MI
2005-present	Professor (w/tenure), Depts of Int Med & Urology, Univ of Michigan Med School, Ann Arbor, MI
2006-2007	Assoc Chief, Div of Hem/Onc, Dept of Int Med, Univ of Michigan Med School, Ann Arbor, MI
2007-2008	Interim Chief, Div of Hem/Onc, Dept of Int Med, Univ of Michigan Med School, Ann Arbor, MI
2009-present	Chief, Div of Hem/Onc, Dept of Int Med, Univ of Michigan Med School, Ann Arbor, MI
2009-present	Assoc Director for Faculty Affairs, Univ of Michigan Comprehensive Cancer Ctr, Ann Arbor, MI
2009-present	Endowed Professorship, Frances and Victor Ginsberg Professor of Hematology/Oncology, Dept of Internal Medicine, University of Michigan Medical School, Ann Arbor, MI
2010-2013	Interim Medical Director, University of Michigan Comprehensive Cancer Center, Ann Arbor, MI
2013-present	Deputy Director for Cancer Clinical Services, University of Michigan Comprehensive Cancer Center, Ann Arbor, MI

#### Other Experience and Professional Memberships

1995-1997	U.S. Army Breast Cancer Research Program Scientific Grant Review
1998	American Cancer Society Molecular Genetics and Oncogenes Study Section
1999-2000	NIH Special Emphasis Panel (EDC-2): Molecular Epidemiology of Prostate Carcinogenesis
1999-2000	U.S. Army Prostate Cancer and Ovarian Cancer Research Programs Scientific Grant Review
2000-2005	NIH Epidemiology of Cancer (EPIC) ad hoc & permanent Study Section Member (formerly EDC-2)
2004-present	Fellow of the American College of Physicians (F.A.C.P.)
2004-7	U.S. Army Prostate Cancer Research Program Integration Panel (ad hoc member)
2007-2010	NIH SPORE Review Panel (ad hoc member)
2007	NIH/NCI Cancer Center Site Review, New York University Cancer Institute

2005-2012 American Society of Clinical Oncology (ASCO) Grants Selection Committee  
2010-2011 Chair, Conquer Foundation of the ASCO Grants Selection Committee  
2010 NIH/NCI Cancer Genetics Study Section (ad hoc member)  
2011-present NIH/NCI Cancer Center Site Reviews  
2011,2014 NIH/NCI IRG Subcommittee A (ad hoc member)  
2012 NIH/NCI SPORE Review Panel, Co-Chair  
2012-present NIH/NCI Cancer Genetics Study Section (permanent member)  
2012-present ASCO Scientific Program Committee

### Honors

1976 Daniel Webster Scholar, Dartmouth College  
1980 Phi Beta Kappa, Dartmouth College  
1984 Lillie M. Erk Prize, University of Pennsylvania School of Medicine  
1988 American Cancer Society Clinical Oncology Fellowship  
1999 Career Development Award, University of Michigan Agenda for Women  
2000 Jerome W. Conn Award for Distinguished Research by Jr. Faculty Member, Department of Internal Medicine, University of Michigan  
2009 Endowed Professorship, Frances and Victor Ginsberg Professor of Hematology/Oncology, Dept of Internal Medicine, University of Michigan Medical School, Ann Arbor, MI  
2010 National Institutes of Health Award of Merit, PDQ Cancer Genetics Editorial Board  
2011 League of Research Excellence, University of Michigan Medical School  
2011 Chairman's Award, Dept of Internal Medicine, University of Michigan Medical School  
2011-present Best Doctors in America

### **C. Selected Peer-Reviewed Publications** (selected from 118 peer-reviewed publications)

#### **Most relevant to the current application**

1. Douglas J, Levin AM, Zuhlke KA, Ray AM, Johnson GR, Lange EM, Wood DP, Cooney KA. Common variation in the *BRCA1* gene and prostate cancer risk. *Cancer Epidemiol Biomarkers Prev* 16(7):1510-1516, 2007. [PM:17585057](#)
2. Levin AM, Ray AM, Zuhlke KA, Douglas JA, Cooney KA. Association between germline variation in the *FHIT* gene and prostate cancer in Caucasians and African Americans. *Cancer Epidemiol Biomarkers Prev* 16(6):1294-1297, 2007. [PM:17548701](#)
3. Beebe-Dimmer JL, Faerber GJ, Morgenstern H, Werny D, Wojno K, Halstead-Nussloch, BA, Cooney KA. Body composition and serum prostate specific antigen: A review and findings from the Flint Men's Health Study. *Urology* 71(4):554-560, 2008. [PM:18308373](#) [PMC2329814](#)
4. Hwang C, Oetjen KA, Kosoff D, Wojno KJ, Albertelli MA, Robins DM, Cooney KA, Duckett CS. X-linked inhibitor of apoptosis deficiency in the TRAMP mouse prostate cancer model. *Cell Death Diff* 15(5):831-840, 2008. [PM:18259199](#) [PMC2710036](#)
5. Levin AM, Machiela MJ, Zuhlke KA, Ray AM, Cooney KA, Douglas JA. Chromosome 17q12 variants contribute to risk of early-onset prostate cancer. *Cancer Res* 68(16):6492-6495, 2008. [PM:18701471](#) [PMC2562290](#)
6. Tischkowitz MD, Yilmaz A, Chen LQ, Karyadi DM, Novak D, Kirchhoff T, Hamel N, Tavtigian SV, Kolb S, Bismar TA, Aloyz R, Nelson PS, Hood L, Narod SA, White KA, Ostrander EA, Isaacs WB, Offit K, Cooney KA, Stanford JL, Foulkes WD. Identification and characterization of novel SNPs in *CHEK2* in Ashkenazi Jewish men with prostate cancer. *Cancer Letters* 270(1):173-180, 2008. [PM:18571837](#) [PMC2969172](#)
7. Wang L, Liu R, Li W, Chen C, Katoh H, Chen G, McNally B, Lin L, Zhou P, Zuo T, Cooney KA, Liu Y, Zheng P. Somatic single-hits inactivate the X-linked tumor suppressor *FOXP3* in the prostate. *Cancer Cell* 16(4):336-346, 2009. [PM:19800578](#) [PMC2758294](#)
8. Ray AM, Zuhlke KA, Johnson GR, Levin AM, Douglas JA, Cooney KA. Absence of truncating *BRIP1* mutations in chromosome 17q-linked hereditary prostate cancer families. *British Journal of Cancer* 101(12):2043-2047, 2009. [PM:19935797](#) [PMC2795448](#)
9. Chang BL, Spangler E, Gallagher S, Haiman CA, Henderson B, Isaacs W, Benford ML, Kidd LR, Cooney K, Strom S, Ingles SA, Stern MC, Corral R, Joshi AD, Xu J, Giri VN, Rybicki B, Neslund-Dudas C, Kibel AS, Thompson IM, Leach RJ, Ostrander EA, Stanford JL, Witte J, Casey G, Eeles R, The UKGPCS Coordinating Group and Collaborators, Hsing AW, Chanock S, Hu JJ, John EM, Park J, Stefflova K,

## BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.  
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Hirsch, Fred R.	POSITION TITLE Professor of Medicine and Pathology		
eRA COMMONS USER NAME (credential, e.g., agency login)			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	MM/YY	FIELD OF STUDY
University of Copenhagen, Denmark	M.D.	1977	Medicine
University of Copenhagen, Denmark	PhD (Dr.med.)	1983	Pathology
University of Business, Copenhagen, Denmark	Diploma	1999	Public Health Admin

**Personal Statement:** After training in medical oncology and pathology from Copenhagen, DK, I moved in 1999 to Denver, CO and have since then built up a CLIA-certified translational science lab with focus on biomarker development and validation for early detection of lung cancer and targeted therapy of lung cancer. My lab is performing assays based on different platforms, i. e. gene copy number by Silver in Situ Hybridization (SISH), Immunohistochemistry, mRNA in situ, miRNA and PCR-based assays. The lab has been focusing on different biomarkers for prognosis and prediction of sensitivity to new targeted therapies, such as EGFR, IGFR, c-MET, MTOR and FGFR. The lab is performing biomarkers in several large clinical trials, both industry driven as well as several SWOG trials. I am co-Chair of SWOG Lung Cancer Group 's Correlative Science Committee. For early detection we are doing studies with miRNAs and in collaboration with a chemistry group in Israel, we are doing studies with exhaled breath based on a specific developed nanoparticle assay (the "E-nose"). I am continuously training/mentoring younger (foreign) oncology fellows, post-docs and younger faculty in lung cancer translational research through the SPORE program.

### B. Positions and Honors.

#### Professional Experience

1989-1991 Associate Professor, Internal Medicine, University of Copenhagen, Denmark  
 1991-1992 Senior Investigator, Department of Oncology, Rigshospitalet, Copenhagen, Denmark  
 1992-1995 Associate Professor, Internal Medicine, University of Copenhagen, Denmark  
 1992-1996 Chief Physician, Department of Medical Oncology, Bispebjerg Hospital, Copenhagen, Denmark  
 1996-2001 Chief Physician, Department of Oncology, Finsen Center, Rigshospitalet, Copenhagen, Denmark  
 1999-2002 Visiting Professor, University of Colorado Cancer Center, Denver, CO, USA  
 2002-present Professor of Medicine, University of Colorado Cancer Center, Denver, CO, USA  
 2004-present Professor of Pathology, University of Colorado Cancer Center, Denver, CO, USA  
 2006-present Professor with Tenure, University of Colorado Cancer Center, Denver, CO, USA  
 2011- Associate Director for International Programs, Univ of Colorado Cancer Center.  
 2013 Executive Director, International Association for the Study of Lung Cancer

#### Honors/Awards

1995-2004 Member of WHO Expert Panel for Classification of Lung Tumors  
 1998-2001 Vice-chairman, EU Early Lung Cancer Detection Committee  
 2000-2006 Chairman, International Association for the Study of Lung Cancer; Prevention Committee  
 2001-2008 Member, Early Lung Cancer Action Program (ELCAP) Advisory Board, New York, USA  
 2001-2008 Member of Coordination Committee: EU/US cooperation for lung cancer CT-screening studies.  
 2002-2008 American Soc. Clin. Oncology: Program-, Publication-, International Affairs Committees.  
 2005-present International Association for the Study of Lung Cancer, Board of Directors  
 2006-2007 American Society for Clinical Oncology. Lung Cancer Track Leader  
 2010- National Cancer Institute/CTEP: Member of Thoracic Oncology Steering Committee  
 2007 IASLC Mary Matthews Distinguished Award for Translational Research in Lung Cancer  
 2010 Japanese Lung Cancer Society: Merit Award 2010

## BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.  
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME <b>KOONG, Albert C.</b>		POSITION TITLE	
eRA COMMONS USER NAME <b>KOONG.ALBERT</b>		Associate Professor	
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	YEAR(s)	FIELD OF STUDY
Stanford University, Stanford, CA	B.S.	1989	Biology
Stanford University School of Medicine	Ph.D.	1994	Cancer Biology
Northwestern University School of Medicine	M.D.	1996	Medicine
Kaiser Permanente, Santa Clara, CA	Internship	1996-1997	Internal Medicine
Stanford University Medical Center	Residency	1997-2001	Radiation Oncology

### A. Personal Statement

My laboratory has had a long-standing interest in understanding the role of the tumor microenvironment on tumor progression. We have focused on a hypoxia and ER stress activated pathway, termed the unfolded protein response (UPR), which plays a critical role in mediating tumor cell survival and promoting angiogenesis. We have utilized various genetic models to show the importance of this pathway in tumor growth. We have also completed a high throughput screen and identified several classes of small molecule inhibitors of this pathway. Additional studies are ongoing to define other signaling pathways that interact with the UPR and to target these pathways as a cancer therapeutic strategy.

My clinical research is focused on the application of advanced radiotherapy technologies for GI malignancies. In particular, I am interested in developing stereotactic body radiotherapy (SBRT) and image guided radiotherapy (IGRT) techniques for the treatment of pancreatic and liver tumors.

### B. Positions and Honors

#### Professional Experience

2001-2009 Assistant Professor, Radiation Oncology, Stanford University Medical School  
2001-present Attending Physician, Radiation Oncology, Stanford University Medical Center  
2009-present Associate Professor, Radiation Oncology, Stanford University Medical School  
2011-present Vice-Chair, Radiation Oncology, Stanford University Medical School  
2014-present Professor, Radiation Oncology Stanford University Medical School

#### Profession Activities/Honors

1999 Chief Resident, Radiation Oncology, Stanford University Medical Center  
1999 Roentgen Resident/Fellow Research Award, Radiological Society of North America  
1999 Resident Clinical/Basic Research Award  
American Society for Therapeutic Radiology and Oncology  
2001 Malcolm A. Bagshaw Award  
2002 ASTRO Junior Faculty Research Award  
2002 Damon Runyon-Lilly Clinical Investigator Award  
2013 Richard T. Hoppe Leadership Award

### C. Selected Peer-Reviewed Publications (total of 126)

1. **Koong AC**, Mehta VK, Le QT, Fisher GA, Terris DJ, Brown JM, Bastidas AJ, Vierra M. Pancreatic tumors show high levels of hypoxia. *Int J Radiat Oncol Biol Phys.* 2000 Nov 1; 48(4): 919-22.
2. **Koong AC**, Le QT, Ho A, Fong B, Fisher G, Cho C, Ford J, Poen J, Gibbs IC, Mehta VK, Kee S, Trueblood W, Yang G, Bastidas JA. Phase I study of stereotactic radiosurgery in patients with locally advanced pancreatic cancer. *Int J Radiat Oncol Biol Phys.* 2004 March 15; 58(4): 1017-21.

**BIOGRAPHICAL SKETCH**

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2.  
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Lu, Ying		POSITION TITLE Professor of Biostatistics, Stanford University Director of Palo Alto Cooperative Studies Program Center, Palo Alto VA Healthcare System	
eRA COMMONS USER NAME (credential, e.g., agency login) YINGLU			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	MM/YY	FIELD OF STUDY
Fudan University, Shanghai, China	B.S.	07/82	Mathematics
Shanghai Jiao Tong University, Shanghai, China	M.S.	07/84	Applied Mathematics
University of California, Berkeley, CA	Ph.D.	06/90	Biostatistics

**A. Personal Statement**

As a statistician, I have worked in cancer research in the past 24 years. From 1999-2009, I worked in the HDF UCSF Comprehensive Cancer Center and directed the biostatistics core from 2002-9. My research interests include new statistical design for various phase of clinical trials, validation of new imaging modalities, medical decision making for personalized diagnostic and treatment decisions. I was a member of AJCC task force, served external advisory boards for the Tufts Medical Center Cancer Center and the UCLA Brain Cancer SPORE application, and various DSMB committees. At Stanford and VA Palo Alto, I direct the Palo Alto VA Cooperative Studies Program Coordinating Center to organize and provide comprehensive support for large multicenter clinical trials, including a trial in prostate cancer. I am also a member of Stanford Cancer Center.

**B. Positions and Honors****Positions and Employment**

2009-present Professor of Biostatistics, Department of Health Research and Policy, Stanford University  
 2009-present Director, Palo Alto Cooperative Studies Program Center, Palo Alto VA Health Care System  
 1994-2009 Assistant (94-98), Associate (98-03) Adjunct Professor, and Associate Professor in Residence (2003-06), Professor in Residence (2006-2009), Director of Biostatistics and Outcome Research Specialized Research Group (2007-2009), Dept of Radiology and Biomedical Imaging; Associate Professor in Residence (2003-06), Professor in Residence (2006-09), Dept of Epidemiology and Biostatistics (2003-2009), University of California, San Francisco, CA  
 2000-2009 Faculty Member, Bioengineering Graduate Program, University of California San Francisco & Berkeley  
 1999-2009 Director (2002-2009), Biostatistics Core Facility; Member of Cutaneous Oncology Program, and GI Oncology Program of the HDF UCSF Comprehensive Cancer Center, University of California, San Francisco, CA  
 1990-1994 Assistant Professor, Department of Epidemiology and Public Health, School of Medicine, University of Miami, Miami, Florida  
 1986-1989 Biostatistician/Analyst. Triton Biosciences, Inc., Alameda, CA 94501  
 1984-1985 Instructor, Dept. of Applied Mathematics, Shanghai Jiao Tong University, Shanghai, China

**Other Experience and Professional Memberships**

1995-2010 Vice President (1995-97), President Elected (1997-98, 2004-05), President (1998-99, 2005-06), Chapter Representative (2006-2010), American Statistical Association San Francisco Bay Area Chapter  
 1995-1999 Member, International Committee on Standardization of Bone Measurement  
 2001-2002 Ad hoc reviewer of project program grant, NIH

2004-2006 Temporary member, Epidemiology of Clinical Disorders and Aging Study Section, NIH;  
2006-2011 Member, NIH Neurological, Aging, & Musculoskeletal Epidemiology (NAME) Study Section  
2006-2009 Member, American Joint Committee on Cancer (AJCC) Statistical Task Force  
2009-present Member, American Joint Committee on Cancer (AJCC) Molecular Modeler Group  
2007-2009 Member, WNAR Regional Committee  
2007-2011 Member, US Food and Drug Administration Peripheral and Central Nervous System Drugs  
Advisory Committee  
2008-present Member, the External Advisory Board of the Tufts Medical Center Cancer Center  
2008-2011 Chair, Program Committee, International Chinese Statistical Association  
2010-present Member, Veterans Administration Centralized Data Monitoring Committee for Phase I Studies  
2012-present Member, VA's Health Services Research and Development Data and Safety Monitoring Board  
2013-present President-elect (2013) and President (2014), International Chinese Statistical Association

### **Honors**

1985-1988 University Fellowship, UC Berkeley, CA  
1989 School of Public Health Alumnus Scholarship, UC Berkeley, CA  
1990 The Evelyn Fix Memorial Medal and Citation, Dept of Statistics, UC Berkeley, CA  
2003 Healthstar Osteoporosis Medical Research Award, the Chinese Development Foundation  
For Science and Technology, Beijing, China  
2009 Exemplary Service Award, UCSF Helen Diller and Family Comprehensive Cancer Center, San  
Francisco, CA  
2010 Advisory Committee Service Award, US Food and Drug Administration, Washington DC  
2011 Elected Fellow, American Statistical Association

### **C. Selected Peer-reviewed Publications** (out of 215 peer-reviewed papers)

#### **Most relevant to the current application**

1. Malani HM, Lu Y. Animal carcinogenicity experiments with and without serial sacrifice. *Communications in Statistics—Theory and Methods* 1993; 22:1557-1584
2. Lu Y, Malani HM. Estimating multiple tumor transition rates based on data from survival/sacrifice experiments. *Mathematical Biosciences* 1994; 122:95-125.
3. Lu Y, Bean JA. On the sample size for studies of bioequivalence based upon McNemar's test. *Statistics in Medicine* 1995; 14:1831-1839
4. Lu Y, Malani HM. Analysis of Animal Carcinogenicity Experiments with Multiple Tumor Types. 1995; *Biometrics* 51:73-86.
5. Sevin B-U, Lu Y, Nadji MN, Bloch D, Koechli OR, Averette HA. Surgically defined prognostic parameters in early cervical carcinoma: A tree structured survival analysis. *Cancer* 1996; 78:1438-1446.
6. Kinkel K, Lu Y, Both M, Warren RS, Thoeni RF. Detection of hepatic metastases from cancers of the gastrointestinal tract using noninvasive imaging methods (US, CT, MRI, FDG PET): a meta-analysis, *Radiology* 2002; 224(3):748-756
7. Lu Y, Jin H, Genant HK. On the equivalence of two diagnostic tests based on paired observations. *Statistics in Medicine* 2003 Oct; 22(10):3029-44. PMID: 12973785
8. Lu Y, Jin H, Lamborn K. Design of phase II cancer trials with both total and complete responses. *Statistics in Medicine* 2005 Oct 30;24(20):3155-70. PMID: 12973785
9. Fan S, Venook AP, Lu Y. Design issues in dose-finding phase I trials for combinations of two agents. *Journal of Biopharmaceutical Statistics* 2009; 19(3): 509-23.
10. Li C and Lu Y. Evaluating the improvement in diagnostic utility from adding new predictors. *Biometrical Journal* 52 (3): 417-435, 2010. PMID: 20496347
11. Lu Y, Fan S. On the Time to Conclusion of Phase II Cancer Clinical Trials and Its Application in Trial Designs. *Statistics in Biopharmaceutical Research*. 2012; 4(4):324-335.
12. Kornak J, Lu Y. Bayesian Decision Analysis for Choosing Between Diagnostic/Prognostic Prediction Procedures. *Statistics and Its Interface*. 2011; 4(1):27-36. PMID: 23243483. NIHMSID #241219

## BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2.  
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Pamela N. Munster		POSITION TITLE	
eRA COMMONS USER NAME (credential, e.g., agency login) munstepn		M.D., Professor of Medicine	
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)			
INSTITUTION AND LOCATION	DEGREE (if applicable)	MM/YY	FIELD OF STUDY
Kantonsschule Sargans, Switzerland	Baccalaureate	1983	Sciences, Liberal Arts
University of Bern, Switzerland	Doctorate	1990	Medicine
University of Bern, Switzerland	M.D. Thesis	1992	Medicine

### A. Personal Statement

My clinical research interests are “first in human” early phase clinical trials of novel compounds and alternative strategies for the treatment and prevention of cancer. As the program leader for Development Therapeutics and a member of the breast program I have extensive experience in translating preclinical findings into early stage clinical trials with extensive PK and PD correlative studies for patients with breast cancer. My experience in drug development with systemic agents has taught me that the current development of anticancer agents may be associated with too many side effects and too little gain for patients at risk for breast cancer desiring prevention. We are now focused on novel strategies to optimize local therapy and minimize systemic toxicities.

My research interest is focused on the role of epigenetic modification in hormone therapy resistance in breast cancer. In addition to studying basic mechanisms of hormone therapy resistance, we have shown that epigenetic modification plays a crucial role in the hormonal regulation and carcinogenesis of breast cancer.

### B. Positions and Honors

#### Positions and Employment

4/1990-5/1992 Postdoctoral Fellow, University of Bern, Department of Physiology, Bern, Switzerland.  
4/1991-5/1992 Chief Postdoctoral Fellow University of Bern, Department of Physiology, Bern, Switzerland  
5/1992-6/1993 Postdoctoral Fellow, Indiana University, Krannert Institute of Cardiology, Indianapolis, IN.  
6/1993-6/1996 Residency in Internal Medicine, Indiana University at Indianapolis, Indiana, IN.  
7/1996-6/2000 Fellowship Hematology/Oncology, Memorial Sloan Kettering Cancer Center/The New York Hospital-Cornell Medical Center, New York, NY.  
Memorial Sloan Kettering Cancer Center, Department of Medicine,  
8/2000-6/2001 Assistant Member, Memorial Sloan Kettering Cancer Center, New York, NY, Breast Cancer Service, New York, NY.  
6/2001-5/2006 Assistant Professor, Division of Breast Oncology & Experimental Therapeutics, Moffitt Cancer Center, Dept of Internal Medicine, University of South Florida, Tampa, FL, Scientific Director, Comprehensive Breast Program  
6/2005-5/2008 Faculty, Cancer Biology PhD Program, University of South Florida, Tampa, FL  
6/2006-5/2008 Associate Professor: Division of Breast Oncology & Experimental Therapeutics, Moffitt Cancer Center, Department of Internal Medicine, University of South Florida, Tampa, FL  
Co-Chair, Phase I Program  
5/2008-6/2010 Associate Professor in Residence, Hematology/Oncology Program, Dep. Medicine, University of California San Francisco, San Francisco, CA, Director Early Phase Clinical Trials Program  
4/2009-present Medical Director for MTZ CRC, Clinical Translational Science Award (CTSA)  
6/2007-present Faculty Affiliate, Colorado State University, Ft. Collins, CO  
7/2010-present Professor in Residence, Hematology/Oncology Program, Department of Medicine

University of California San Francisco, San Francisco, CA, Program Leader Developmental Therapeutics, Associate Director, Investigational Therapeutics Initiative,

### **Honors:**

1998 John Mendelsohn House staff Teaching Award  
1999 AACR-AFLAC Young Investigators Scholar Award 1999  
2000 Byrne Fund Award  
2003 Don Shula Career Development Award, 2003-2005  
2007, 2008 Moffitt Cancer Center, Greatest Number of Investigator-Initiated Trials Written & Implemented  
2008 Research Highlights, Department of Defense, Congressionally Directed Medical Research Programs

### **Other Experiences and Professional Memberships**

BioMedical Graduate Program, University of California, San Francisco

Faculty Advisor, University of Copenhagen, Denmark

Faculty Advisor, Colorado State University, Ft. Collins,

CO Editorial Board: Journal of Clinical Oncology

Associate Editor: Clinical Epigenomics

NCI/NHI review: Chartered Member, Development therapeutics Study section,

NCI/NIH Ad Hoc Member for P01, P30 and Special Emphasis

Panels

Alliance (NCCTG, CALGB, ACOSOG) Committee Member for Experimental Therapeutics

### **Selected Peer-reviewed Publications (Selected from 75 peer-reviewed Publications)**

1. **Münster PN**, Buzdar A, Dhingra K, Enas N, Ni L, Major M, Melemed A, Seidman A, Booser D, Theriault R, Norton L, Hudis C. Phase I Study of a Third-Generation Selective Estrogen Receptor Modulator, LY353381.HCl, in Metastatic Breast Cancer. *J Clin Oncol.* 19 (7):2002-2009, 2001. PMID:11283133
2. **Münster PN**, Troso-Sandoval T, Rosen N, Rifkind R, Marks PA and Richon, VM. Histone Deacetylase Inhibitor Suberoylanilide Hydroxamic Acid Induces Differentiation of Human Breast Cancer Cells: *Cancer Research*, Dec 1;61(23):8492-7
3. Basso A, Solit D, **Münster PN** and Rosen N. Ansamycin Antibiotics Inhibit Akt Activation and Tumor Growth in Human Breast Cancers That Overexpress HER2. *Oncogene.* 2002 Feb 14;21(8):1159-66.
4. **Münster PN**, Marchion D, Basso A and Rosen N. Degradation of HER2 by Ansamycins Induces Growth Arrest and Apoptosis in Cells with HER2 Overexpression via a Phosphatidylinositol 3'- Kinase-AKT- dependent Pathway. *Cancer Res.* 62: 3132-7., 2002.
5. Marchion DC, Bicaku E, Daud AI, Sullivan DM and **Münster PN**. Valproic Acid Alters Chromatin Structure by Regulation of Chromatin Modulation Proteins. *Cancer Res*, May 2005 65: (9):3815-22.
6. Marchion DC, Bicaku E, Turner JG, Daud AI, Sullivan DM and **Münster PN**. Synergistic interaction between HDAC and topo II inhibitors is mediated through topo II $\beta$ . *Clin Cancer Res.* 2005 Dec 1;11(23):8467-75.
7. **Münster PN**, Britten CD, Mita M, Gelmon K, Minton SE, Moulder S, Slamon DJ, Guo F, Letrent SP, Denis L and Tolcher AW. First Study of the Safety, Tolerability and Pharmacokinetics of CP-724,714 in Patients with Advanced Malignant Solid HER2-expressing tumors. *Clin Cancer Res.* 2007 Feb 15;13(4):1238-45.
8. **Münster PN**, Marchion DC, Bicaku E, Schmitt M, Deconti R, Simon G, Fishman M, Minton S, Garrett C, Chiappori A, Lush R, Sullivan D, and Daud A. Phase I trial of histone deacetylase inhibition by valproic acid (VPA) followed by the topoisomerase II inhibitor epirubicin in advanced solid tumors: A clinical and translational study. *J Clin Oncol.* 2007 May 20;25(15):1979-85.
9. **Münster PN**, Marchion D, Bicaku E, Lacevic M, Kim J, Centeno B, Daud A, Neuger A, Minton S, Sullivan D. Clinical and biological effects of valproic acid as a histone deacetylase inhibitor on tumor and



## BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.  
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Oliver W. Press	POSITION TITLE Professor of Medicine, University of Washington Member, Fred Hutchinson Cancer Research Center		
eRA COMMONS USER NAME (credential, e.g., agency login) OPRESS			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	MM/YY	FIELD OF STUDY
Stanford University, Stanford, CA	B.S.	06/73	Biology
University of Washington, Seattle, WA	Ph.D.	06/77	Biological Structure
University of Washington, Seattle, WA	M.D.	06/79	Medicine
Massachusetts General Hospital, Boston, MA		06/82	Medicine Internship & Residency
University of Washington, Seattle, WA		06/83	Chief Resident in Medicine

### Positions:

1979-1980 Internship, Massachusetts General Hospital, Boston  
 1980-1982 Residency, Massachusetts General Hospital, Boston  
 1979-1982 Clinical Fellow in Medicine, Harvard Medical School, Boston  
 1982-1983 Chief Resident, University of Washington Medical Center, Seattle  
 1982-1986 Acting Instructor in Medicine, University of Washington, Seattle  
 1983-1986 Postdoctoral Fellow, UWMC and Fred Hutchinson Cancer Research Center, Seattle  
 1983-1986 Associate in Clinical Research, Fred Hutchinson Cancer Research Center, Seattle  
 1986-1991 Assistant Member, Fred Hutchinson Cancer Research Center, Seattle  
 1987-1991 Assistant Professor in Medicine, University of Washington, Seattle  
 1988-1991 Adjunct Assistant Professor of Biological Structure, University of Washington  
 1990-2006 Associate Director, Medical Scientist (MD/PhD) Training Program  
 1991-1996 Associate Professor in Medicine and Biological Structure, University of Washington  
 1991-1996 Associate Member, Fred Hutchinson Cancer Research Center, Seattle  
 1993-2000 Acting Program Director, High Dose Chemotherapy Service, Univ. of Washington  
 1996-2009 Adjunct Professor of Biological Structure, University of Washington  
 1996-Present Professor of Medicine, University of Washington  
 1996-Present Member, Fred Hutchinson Cancer Research Center, Seattle  
 2006-2009 Director, Clin. Research Hematology & Hematologic Malignancies, Seattle Cancer Care Alliance  
 2009-Present Co-Director, Center for Intracellular Delivery of Biologics, University of Washington  
 2009-Present Co-Director, Training Program in Nanotechnology and Physical Sciences in Cancer Research, University of Washington  
 2012-Present Adjunct Professor of Bioengineering, University of Washington  
 2013-Present Acting Senior Vice President, Fred Hutchinson Cancer Research Center  
 2013-Present Acting Director and Member, Clinical Research Division, FHCRC

### Honors:

1970-1973 George E. Gamble Honors Scholarship, Stanford University  
 1973 Phi Beta Kappa, Stanford University  
 1973 Departmental Honors and Departmental Distinction in Biology, Stanford University  
 1969-1973 Dean's List of Honors Students, Stanford University  
 1976 Alpha Omega Alpha, Honorary Medical Fraternity (elected as 3rd year student)  
 1978 Scholarship from International College of Surgeons  
 1979 PhD Thesis Honors  
 1979 Graduation with "Highest Honors" University of Washington School of Medicine  
 1979 Seattle Academy of Internal Medicine Prize  
 1985-1986 Young Investigator Award from the American Society for Clinical Oncology  
 1985-1988 Clinical Oncology Career Development Award from the American Cancer Society  
 1987-1992 First Independent Research and Training Award from the National Institutes of Health  
 1996-present Election to American Society of Clinical Investigation

- 2000-present Election to American Association of Physicians
- 2000-present Recipient, Dr. Penny E. Petersen Memorial Chair for Lymphoma Research
- 2007 Ellen Glesby Cohen Leadership Award, Lymphoma Research Foundation
- 2005-2008 Chairman, Scientific Advisory Board, Lymphoma Research Foundation
- 2008-present Chairman, Follicular Lymphoma Consortium, Lymphoma Research Foundation
- 2009 Freundlich Leadership Award, Lymphoma Research Foundation
- 2009-Present Co-Chair, National Cancer Institute Lymphoma Steering Committee
- 2010-2014 Member, American Society of Hematology, Scientific Committee on Lymphoid Neoplasia
- 2013-2014 Chair, American Society of Hematology, Scientific Committee on Lymphoid Neoplasia

**Selected Peer-reviewed Publications (Selected from >200 peer-reviewed publications)**

1. **Press OW**, Palanca-Wessels MC. Selection of First-Line Therapy for Advanced Follicular Lymphoma. *J Clin Oncol.* 2013;31:1496-8. PMID – In Process
2. Green DJ, Orgun NN, Jones JC, Hylarides MD, Pagel JM, Hamlin DK, Wilbur DS, Lin Y, Fisher DR, Kenoyer AL, Frayo SL, Gopal AK, Orozco JJ, Gooley T, Wood BL, Bensinger W, **Press OW**. A preclinical model of CD38-pretargeted radioimmunotherapy for plasma cell malignancies. *Cancer Res.* 2013 Dec 26. [Epub ahead of print]
3. Budde LE, Berger C, Lin Y, Wang J, Lin X, Frayo SE, Brouns SA, Spencer DM, Till BG, Jensen MC, Riddell SR, **Press OW**. Combining a CD20 Chimeric Antigen Receptor and an Inducible Caspase 9 Suicide Switch to Improve the Efficacy and Safety of T Cell Adoptive Immunotherapy for Lymphoma. *PLoS One.* 2013 Dec 17;8(12):e82742. PMID: PMC3866194.
4. **Press OW**, Unger JM, Rimsza LM, Friedberg JW, LeBlanc M, Czuczman MS, Kaminski M, Braziel RM, Spier C, Gopal AK, Maloney DG, Cheson BD, Dakhil SR, Miller TP, Fisher RI. A Phase III Randomized Intergroup Trial of CHOP Chemotherapy Plus Rituximab Compared to CHOP Chemotherapy Plus <sup>131</sup>Iodine-Tositumomab for Previously Untreated Follicular Non-Hodgkin's Lymphoma (SWOG S0016). *J Clin Oncol.* 2013 31:314. PMID: PMC3732010
5. Till BG, Jensen MC, Wang J, Qian X, Gopal AK, Maloney DG, Lindgren CG, Lin Y, Pagel JM, Budde LE, Raubitschek A, Forman SJ, Greenberg PD, Riddell SR, **Press OW**. CD20-specific adoptive immunotherapy for lymphoma using a chimeric antigen receptor with both CD28 and 4-1BB domains: pilot clinical trial results. *Blood.* 119:3940, 2012. PMID: PMC3350361
6. Park SI, Shenoi J, Frayo SM, Hamlin DK, Lin Y, Wilbur DS, Stayton PS, Orgun N, Hylarides M, Buchegger F, Kenoyer AL, Axtman A, Gopal AK, Green DJ, Pagel JM, **Press OW**. Pretargeted radioimmunotherapy using genetically engineered antibody-streptavidin fusion proteins for treatment of non-Hodgkin lymphoma. *Clin Cancer Res.* 17:7373, 2011. PMID: PMC3229652.
7. Palanca-Wessels MC, Convertine AJ, Cutler-Strom R, Booth GC, Lee F, Berguig GY, Stayton PS, **Press OW**. Anti-CD22 antibody targeting of pH-responsive micelles enhances small interfering RNA delivery and gene silencing in lymphoma cells. *Molecular Therapy.* 19:1529, 2011. PMID: PMC3149160
8. Pagel JM, Kenoyer AL, Bäck T, Hamlin DK, Wilbur DS, Fisher DR, Park SI, Frayo S, Axtman A, Orgun N, Orozco J, Shenoi J, Lin Y, Gopal AK, Green DJ, Appelbaum FR, **Press OW**. Anti-CD45 pretargeted radioimmunotherapy using bismuth-213: high rates of complete remission and long-term survival in a mouse myeloid leukemia xenograft model. *Blood.* 118:703, 2011. PMID: PMC3142907
9. Gopal AK, Guthrie KA, Rajendran J, Pagel JM, Oliveira G, Maloney DG, Matesan M, Storb RF, **Press OW**. <sup>90</sup>Y-ibritumomab tiuxetan, fludarabine, and TBI based non-myeloablative allogeneic transplant conditioning for patients with persistent high-risk B-cell lymphoma. *Blood* 118:1132, 2011. PMID: PMC3673760
10. Park SI, Shenoi J, Pagel JM, Hamlin DK, Wilbur DS, Orgun N, Kenoyer AL, Frayo S, Axtman A, Bäck T, Lin Y, Fisher DR, Gopal AK, Green DJ, **Press OW**. Conventional and Pretargeted Radioimmunotherapy Using Bismuth-213 to Target and Treat Non-Hodgkin Lymphomas Expressing CD20: A Preclinical Model towards Optimal Consolidation Therapy to Eradicate Minimal Residual Disease. *Blood* 116:4231, 2010. PMID: PMC2993626
11. Wilbur DS, Park SI, Chyan MK, Wan F, Hamlin DK, Shenoi J, Lin Y, Wilbur SM, Buchegger F, Pantelias A, Pagel JM, **Press OW**. Design and synthesis of bis-biotin-containing reagents for applications utilizing monoclonal antibody-based pretargeting systems with streptavidin mutants. *Bioconjug Chem,* 21:1225, 2010. PMID: PMC2912428
12. James SE, Greenberg PD, Jensen MC, Lin Y, Wang J, Budde LE, Till BG, Raubitschek AA, Forman SJ, **Press OW**. Mathematical modeling of chimeric TCR triggering predicts the magnitude of target lysis and its impairment by TCR downmodulation. *J Immunol* 184:4284, 2010. PMID: PMC2896691
13. James SE, Orgun NN, Tedder TF, Shlomchik MJ, Jensen MC, Lin Y, Greenberg PD, **Press OW**. Antibody

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Program Director/Principal Investigator (Last, First, Middle):

Shah, Neil Pravin

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## **BIOGRAPHICAL SKETCH**

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NAME Shah, Neil Pravin		POSITION TITLE Associate Professor of Medicine	
eRA COMMONS USER NAME (credential, e.g., agency login) neilshah			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	YEAR(s)	FIELD OF STUDY
University of California, Berkeley	B.S.	1984	Genetics
University of California, Los Angeles	PhD	1992	Microbiology and Molecular Genetics
UCLA School of Medicine	MD	1996	Medicine
UCLA School of Medicine	Intern	1996-1997	Internal Medicine
UCLA School of Medicine	Fellow	1998-2003	Hematology/Oncology

### **A. Personal Statement**

The overarching goals of my research are to identify and override mechanisms of resistance to small molecule tyrosine kinase inhibitors used for the treatment of human myeloid malignancies. I have extensive previous experience performing translational studies with clinically-active kinase inhibitors for the treatment of hematologic malignancies. These studies have provided definitive evidence for the phenomenon of oncogene addiction in human CML and AML. As a postdoctoral fellow in the laboratory of Charles Sawyers at UCLA, I identified resistance-conferring kinase domain mutations within BCR-ABL, the target of imatinib, as the most common mechanism of clinical resistance to this tyrosine kinase inhibitor (TKI) in chronic myeloid leukemia (CML) patients. I then performed the first preclinical studies demonstrating the promise of BMS-354825 (dasatinib) for the treatment of imatinib-resistant CML, and was involved with its clinical development from the phase I first-in-human study through subsequent phase III studies that led to its accelerated approval by the US FDA in 2006 for imatinib-resistant or -intolerant CML. In an effort to expand the successful BCR-ABL TKI paradigm to other hematologic malignancies, I have recently devoted an increasing proportion of my efforts to preclinical and clinical studies with potent FLT3 inhibitors in AML, and to identifying mechanisms of resistance to clinically active agents. Recent data from my lab validates FLT3-ITD as a therapeutic target in human AML. I have extensive experience serving as the Principal Investigator on early phase clinical trials with TKIs, including inhibitors of BCR-ABL, JAK2, and FLT3, and performing translational studies with this class of targeted therapeutics. In recognition of my contributions to the field of TKI therapy in hematologic malignancies, I received a Leukemia & Lymphoma Society Scholar in Clinical Research Award.

### **B. Positions and Honors**

#### **Positions and Employment**

1984-1987	Staff Research Associate, Division of Hematology and Oncology, UCLA
2003-2004	Associate Physician, Division of Hematology and Oncology, The David Geffen School of Medicine at UCLA
2004-2006	Visiting Assistant Professor, Division of Hematology and Oncology, The David Geffen School of Medicine at UCLA
2006-2011	Assistant Professor, Division of Hematology/Oncology, UCSF School of Medicine
2010-2011	Co-leader, Program in Hematopoietic Malignancies, UCSF Cancer Center
2011-present	Associate Professor, Division of Hematology/Oncology, UCSF School of Medicine
2011-present	Edward S. Ageno Distinguished Professor in Hematology/Oncology, UCSF
2012-present	Leader, Program in Hematopoietic Malignancies, UCSF Cancer Center

#### **Honors**

1995	Alpha Omega Alpha Medical Student Research Prize
2004	AACR Scholar-in-Training Award

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## BIOGRAPHICAL SKETCH

NAME Sarah P. Thayer, M.D., Ph.D.	POSITION TITLE Associate Professor of Surgery; Director, Pancreatic Biology Laboratory, Mass. General Hospital, Boston.		
eRA COMMONS USER NAME (credential, e.g., agency login) SPTHAYER	5/2014: Merle M. Musselman Centennial Professor of Surgery; Physician-in-Chief, Fred & Pamela Buffett Cancer Center; Chief, Division of Surgical Oncology, University of Nebraska Medical Center, Omaha, Nebraska		
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)			
INSTITUTION AND LOCATION	DEGREE (if applicable)	YEAR(s)	FIELD OF STUDY
Earlham College, Richmond, Indiana	B.A.	1985	Biology
Georgetown University, Washington, DC	M.S.	1987	Physiology & Biophysics
Univ. of Virginia School of Med., Charlottesville	M.D.	1991	Medicine
Massachusetts General Hospital, Boston		1991-94	Resident in Surgery
Massachusetts General Hospital, Boston		1998-2000	Resident in Surgery
Cornell Univ. Grad. School of Medical Sciences	Ph.D.	1999	Neuroscience
Massachusetts General Hospital, Boston		2000-01	Chief Resident, Surg/Onc.

### A. Personal Statement

The focus of the Thayer laboratory has been to investigate the genes that may contribute to the initiation, progression and regulation of pancreatic cancer. My early work focused on the early and late role of a developmental gene, Shh, in pancreatic cancer (*Nature* 2003). This work revealed that Shh is upregulated early in pancreatic carcinogenesis and in response to chronic inflammatory injury. Although Shh plays an important later role in the biology of pancreatic cancer, it has an equally important early role as an initiator, driving the formation of mucinous ductal lesions resembling early precursor lesions to cancer. My lab has since focused further on characterizing the cell of origin responsive to Shh and the mechanism behind pancreatic regeneration in response to inflammatory injury, and how these may contribute to the formation of pancreatic cancer precursor lesions, and ultimately to cancer. My group was the first to categorize and classify three distinct forms of metaplastic ductal lesions formed in the regenerative response to chronic inflammation (*PNAS* 2007) and their role in regeneration and cancer. Using a chronic inflammatory injury model in combination with *in vivo* lineage tagging, we demonstrated that the beta cell (*PNAS* 2007) and acinar cell (*Gastroenterology* 2007) compartments regenerate by self-renewal. We went on to demonstrate that these compartments do not transdifferentiate and do not contribute to the formation of metaplastic ductal lesions, and thus are an unlikely cell of origin for pancreatic cancer. Most recently, investigation of Shh has called our attention to a novel pancreatic epithelial compartment which we have termed pancreatic duct glands (PDG) (*Gastroenterology* 2010). This work shows that PDG are a mucinous compartment with a distinct molecular signature, expressing many developmental genes believed to mark stem cell compartments. These PDG also undergo a Shh-mediated mucinous gastrointestinal metaplasia resembling certain features of pancreatic cancer precursor lesions. We propose that PDG provide a link between Shh, mucinous metaplasia and neoplasia.

### B. Positions and Honors

#### Positions and Employment

2000-2001	Chief Surgical Resident, Assistant in Surgery, Massachusetts General Hospital
2001-2003	Assistant in Surgery, Surgical Service, Massachusetts General Hospital
2001-2004	Instructor in Surgery, Harvard Medical School
2003-2009	Assistant Surgeon, Surgical Service, Massachusetts General Hospital
2004-	Assistant Professor of Surgery, Harvard Medical School
2008-	Director, Pancreatic Biology Research Laboratory, Massachusetts General Hospital
2009-	Associate Visiting Surgeon, Surgery Service, Massachusetts General Hospital
2010-	Associate Professor of Surgery, Harvard Medical School
2014- (May 1)	Merle M. Musselman Centennial Professor of Surgery; Physician-in-Chief, Fred and Pamela Buffett Cancer Center; Chief, Division of Surgical Oncology, University of Nebraska Medical Center, Omaha, Nebraska

Imaging Technology and Informatics  
Sanjiv “Sam” Gambhir, M.D./Ph.D., Chair

Peer Review Panel Members for Approval

1. James Babilion, Ph.D.
2. Kattesh Katti, Ph.D., D.Sc.
3. Jonathan Liu, Ph.D.
4. Robert Mattrey, M.D., Ph.D.
5. Duane Mitchell, M.D., Ph.D.
6. Shimon Weiss, D.Sc.
7. Anna Wu, Ph.D.
8. Kurt Zinn, Ph.D., D.V.M

## BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.  
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME <b>Basilion, James P.</b>	POSITION TITLE <b>Professor</b>		
eRA COMMONS USER NAME <b>JBASILION</b>	<b>Case Western Reserve University School of Medicine and School of Engineering</b>		
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	YEAR(s)	FIELD OF STUDY
University of Pennsylvania, Philadelphia, PA University of Texas Graduate School of Biomedical Sciences, Houston, TX	BA PhD	1984 1990	Biochemistry Molecular Pharmacology
NIH-NICHD, Cell Biology and Metabolism Branch NIH-NICHD, Cell Biology and Metabolism Branch	Staff Fellow IRTA	1990-1994 1994-1996	Iron Metabolism Iron Metabolism

### A. Personal Statement

I am a molecular biologist/geneticist who has worked at CMIR/MGH with Dr. Weissleder on the development of imaging agents for several years and have gotten insights into the issues surrounding probe design and pharmacology, particularly with optical imaging agents. Seven years ago I moved to Case Western Reserve University to become faculty at both the Case Center for Imaging Research (Department of Radiology, Case Medical School) and at the Department of Biomedical Engineering (Case School of Engineering). I also co-direct the Cancer Imaging Program for the Case Comprehensive Cancer Center and direct the NFCR Center for Molecular Imaging at Case. My academic research career has been devoted to the study and understanding of different diseases for the purposes of detecting them earlier and effecting surgical or other cures. Our lab studies imaging of parasitic disease, of various and numerous different human cancers, of different inflammatory responses, and we have developed technologies to identify and image molecular profiles of said diseases. The common thread to these studies has always been molecular imaging and development of novel imaging probes and paradigms to image these diseases non-invasively and in real time. For our research we utilize most imaging modalities including, MRI, PET, and optical imaging. For the past six years I have developed significant expertise within our laboratory in the development and implementation of FL-microscopic, optical, MR and PET imaging technologies, making my lab qualified to perform and manage these studies.

My research career has been hybrid consisting of experience in the biotech industry in addition to my academic position, which started in the late 1990s. My experience in industry has influenced my perspectives and my laboratory conducts approximately half translational research. My combined industrial and academic position provide me a unique perspective from which to review grants submitted to the CPRIT.

### B. Employment, honors

1989	Thirteenth Annual Meeting of Texas Pharmacologists, First Place Award for Oral Presentation
1989	Consultant to Retinoid Division, Allergan Pharmaceutical, Irvine, CA
1990-1997	Consultant to Biotechnology Group, Janux Group Inc., Greenbelt, MD
1990-1994	Staff Fellow, National Institute of Health, NICHD, Bethesda, MD (Mentors: R.D. Klausner, J. Harford, T. Rouault)
1994-1996	Intramural Research Training Award (IRTA), National Institute of Health, NICHD, Bethesda, MD (Mentors: R.D. Klausner, T. Rouault)
1990-1996	Post Doctoral Fellowship, National Institutes of Health/NICHD; Dr. R. Klausner's lab

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1996-1999	Senior Scientist, Variagenics, Inc., Cambridge, MA
1996-1999	Visiting Research Scientist, Harvard Medical School, Massachusetts General Hospital
1999-2005	Staff Scientist (Molecular Biology), CMIR, Massachusetts General Hospital
1999-2005	Assistant Professor of Radiology, Harvard Medical School
2000-2005	Co-Director, National Foundation for Cancer Research, Center for Molecular Analysis and Imaging, Massachusetts General Hospital/Harvard Medical School, Boston, MA
2005-2013	Associate Professor of Radiology, Case Western Reserve University Medical School
2005-2013	Associate Professor of Biomedical Engineering, Case Western Reserve University School of Engineering
2005-date	Director, National Foundation for Cancer Research Center for Molecular Imaging at Case Western Reserve University
2008-date	Co-founder and Consultant for Akrotome Imaging Inc.
2009-date	Co-Director Cancer Imaging Program, Case Comprehensive Cancer Center, Case Western Reserve University
2013-date	Professor of Radiology, Case Western Reserve University Medical School
2013-date	Professor of Biomedical Engineering, Case Western Reserve University School of Engineering
2013-date	Co-Director Case Center for Imaging Research, Case Western Reserve University
2013	Distinguished Investigator Award, Academy of Radiology Research
2014	Elected Fellow to the American Institute for Medical and Biomedical Engineering (AIMBE)

### C. Selected Publications

#### Most relevant to the current application

1. Cutter JL, Cohen NT, Wang J, Sloan AE, Cohen AR, Panneerselvam A, Schluchter M, Blum G, Bogoy M, **Basilion JP**. Topical application of activity-based probes for visualization of brain tumor tissue. PLoS One. 2012;7(3):e33060. Epub 2012 Mar 13. PubMed PMID: 22427947; PubMed Central PMCID: PMC3302795.
2. Cheng Y, Meyers JD, Agnes RS, Doane TL, Kenney ME, Broome AM, Burda C, **Basilion JP**. Addressing Brain Tumors with Targeted Gold Nanoparticles: A New Gold Standard for Hydrophobic Drug Delivery? Small. 2011 Jun 1. doi: 10.1002/smll.201100628. [Epub ahead of print] PubMed PMID: 21630446.
3. Cheng Y, Meyers JD, Broome AM, Kenney ME, **Basilion JP**, Burda C. Deep penetration of a PDT drug into tumors by noncovalent drug-gold nanoparticle conjugates. J Am Chem Soc. 2011 Mar 2;133(8):2583-91. Epub 2011 Feb 4. PubMed PMID: 21294543; PubMed Central PMCID: PMC3056176.
4. Burden-Gulley SM, Qutaish MQ, Sullivant KE, Lu H, Wang J, Craig SE, **Basilion JP**, Wilson DL, Brady-Kalnay SM. Novel cryo-imaging of the glioma tumor microenvironment reveals migration and dispersal pathways in vivid three-dimensional detail. Cancer Res. 2011 Sep 1;71(17):5932-40. Epub 2011 Aug 23. PMCID: PMC3173511. (*Image selected for Journal Cover*).
5. **Basilion JP**, Agnes RS, Broome AM, Wang J, Verma A, Lavik K. An Optical Probe for Non-invasive Molecular Imaging of Orthotopic Brain Tumors Overexpressing Epidermal Growth Factor Receptor. (2012) Mol Cancer Ther. 2012 Jul 17.

#### Additional recent publications of importance to the field (in chronological order)

1. Weissleder R, Moore A, Mahmood U, Bhorade R, Benveniste H, Chiocca EA, **Basilion JP**. In vivo

**BIOGRAPHICAL SKETCH**

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2.

Follow this format for each person **DO NOT EXCEED FOUR PAGES**

NAME <b>Katti, Kattesh. V., PhD, DSC</b>	POSITION TITLE <b>Professor, Radiology; Professor, Physics; Professor of Biological Engineering, Director, MU Nanoparticles Production Core Facility</b>		
eRA COMMONS USER NAME (credential, e.g., agency login)			
EDUCATION/TRAINING ( <i>Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.</i> )			
INSTITUTION AND LOCATION	DEGREE (if applicable)	YEAR(s)	FIELD OF STUDY
Karnataka University, Dharwad, India	B.S.	1977	Chemistry, Physics, Mathematics
Mysore University, Mysore, India	MSc.Ed.	1979	Chemistry, Science Education
Indian Institute of Science, Bangalore, India	Ph.D.	1984	Chemistry/Polymer Science
University of Gottingen, Humboldt Fellow, Germany	Postdoc	1987	Organic Met Chemistry, Catalysis
University of Alberta, Edmonton, Canada	Postdoc	1990	Organic Chemistry; Organic Met Chemistry
Karnatak University, India	DSC(Hon)	2009	Nanomedicine/Green
Sam Higginbottom University, Allahabad, India	DSC (Hons)	2012	Nanotechnology

**A. Personal Statement:** I am the Margaret Proctor Mulligan Endowed Distinguished Professor of Medical Research, Curators' Professor of Radiology & Physics and Senior Research Scientist at the MU Research Reactor; Director of NCI funded Cancer nanotechnology Platform. I have proven experience as a singly principal investigator projects as well as in facilitating extensive collaborative efforts to drive large biomedical projects through interdisciplinary participant investigators with the overall goal of clinically translating basic sciences findings for clinical applications for ultimately treating human patients. My background and expertise in bioconjugation chemistry, pharmacokinetics, nanomedicine and radiopharmaceutical sciences have allowed me to provide leadership in the production, toxicology and comparative oncology aspects—all aimed at clinical translation of diagnostic and therapeutic agents based on radiopharmaceuticals, biocompatible nanoparticles or phytochemicals. I have been at the forefront of in the development of a plethora of biocompatible nanoparticles for the detection and treatment of cancer and bacterial infections. I have established a Nanoparticle Particle Core Facility, (NPCF), within the University of Missouri, which is the only on-campus production facility of its kind in the country. Specifically, I have discovered processes for the production of gold, palladium, and silver nanoparticles using biologically-friendly phytochemicals from Soy, Tea, Cinnamon, mangoes and a diverse range of medicinal plants and herbs. My research has garnered world-wide attention due to the biocompatibility and environmentally-friendly nature of this discovery. Typically, nanoparticles are produced using toxic synthetic chemicals, and researchers are worried about the in vivo toxic and environmental impacts of production methods. The elements and phytochemicals used in our green nanotechnology processes are naturally occurring non-toxic phytochemicals capable of transforming silver and gold salts into their corresponding nanoparticles. The NCI funded Cancer Nanotechnology Platform, the Nanoparticle Production Core Facility and the University of Missouri Research Reactor are extremely important research capacity infrastructures for our continued success in the application of engineered nanoparticles for biomedical applications. Currently three clinical nanomedicine technologies developed within my NIH/NCI funded programs are going through clinical translation; namely: (i) Prostate tumor therapy through 'non-seed' radioactive gold nanotherapeutic agent; (ii) single circulating tumor cell detection through photoacoustic techniques from human cancer cells; (iii) X ray therapy using targeted gold nanoparticles. I am the principal inventor on over 50 patents and published over 250 publications, reviews, book and chapters.



**Pathway Toward Product Development and Commercialization:** Over the last 25 years, I have been involved in various biomedical projects with a focus on new product development. Specifically, these projects include development of trimeric peptides, proteins, enzymes for use as biomaterials. I am the principal inventor on a patented technology that allows conversion of proteins/enzymes into their corresponding trimeric structures. I have pioneered the development of cancer diagnostic and therapy agents using radioisotopes, development of a gold-containing chemotherapeutic agent for prostate tumor therapy, and development of a chelate for applications in the treatment of Wilson's . I have also worked on projects to validate experimental drugs in collaboration with major pharmaceutical companies including Mallinckrodt Medicals St Louis, DuPont Merck Boston, Proctor Gamble Cincinnati, Upjohn Pharma Boston and Shasun Pharma India. My latest research involves the application of nanotechnology for diagnosis and therapy of cancer and various debilitating diseases. This nanomedicine project involves utility of target specific gold nanoparticles, incorporating receptor specific peptides, and various biomolecules, for diagnosis and therapy of cancers, osteo and rheumatoid arthritis. I have served as the principal/co-inventor in over 50 patents filed/issued in each of the above mentioned projects. I have provided leadership in establishing several start-up companies for commercialization of various biomedical products and have successfully raised capital from the federal and private investments.

## B. Positions and Honors

List in chronological order previous positions, concluding with the present position. List any honors. Include present membership on any Federal Government public advisory committee.

### Positions:

1990-1993 Research Assistant Professor, Dept of Radiology, School of Medicine, University of Missouri-Columbia (MU)  
1990-1997 Research Scientist, Research Reactor, MU  
1993-1996 Assistant Professor, Radiology, School of Medicine, MU  
1996-2000 Associate Professor (Tenure), Radiology, School of Medicine, MU  
1997-present Senior Research Scientist, Research Reactor, MU  
1999-present Associate Director, Radiopharmaceutical Sciences Institute, MU  
2000-2002 Associate Professor, Physics, MU  
2002-present Professor, Radiology and Physics, MU  
2003-present Director, Radiochemistry and Bioconjugation Core Facility, MU  
2005-present Director, Nanoparticles Production Core Facility, MU  
2005-present Director, NCI-Funded Cancer Nanotechnology Platform  
2011-present Professor of Biological Engineering  
2012-present Professor of Medical Pharmacology and Physiology  
2013-present Director, Institute of Green Nanotechnology

### Honors:

1985 Alexander von Humboldt Fellow, Gottingen, Germany  
1995 Fellow of the Royal Society of Chemistry, London  
2005 Gauss Professor, German/Gottingen Academy of Science  
2007 Inducted as Fellow, St. Louis Academy of Science  
2007 St Louis Academy of Science 2007 Outstanding Scientist Award  
2008 Outstanding Missourian Award by Missouri House of Representatives  
2008 Selected as One of '25 Most Influential Molecular Imaging Scientists' in the world by rt Image  
2008 Margaret Proctor Mulligan Distinguished Professor of Medical Research  
2009 Awarded Doctor of Science (DSC) Honorary Degree by Karnataka University, Dharwad, India  
2009 Awarded Curator's Professorship, Highest Academic Status of the Univ. of Missouri System  
2010 One of 10 Best Inventions of 2010 Award for a Green Nanotechnology Invention that involved the production of gold nanoparticles using phytochemicals in Cinnamon.  
2011 Awarded University of Missouri System's Presidential Award for Economic Development  
2012 Inducted as a 'Fellow of The Academy of Science', St Louis  
2012 Awarded Doctor of Science (DSC) Honorary Degree from the Sam Higginbottom University of Agriculture, Technology and Sciences (SHIATS), India

2012 Elected as a Fellow of the American Association for the Advancement of Science (AAAS)

**Committees:**

2006-present Member, Indo-US Science & Technology Forum

2005-present Member, NIH/NCI Study Sections: R01/R21/SBIR Cancer Nanotechnology Special Emphasis Panels (2005-present); Development Therapeutics Study Section/Special Panels (2008-present); SBIR Grants Study Section (2009-present); Ruth L. Kirschstein National Research Service Awards Review Panel (2006-present)

**C. Selected Peer-reviewed Publications (from over 250 peer reviewed publications, reviews and peer reviewed abstracts )**

1. Nune SK, Chanda N, Shukla R, Katti K, Kulkarni RR, Thilakavathi S, Sieckman G, Kannan R, Katti KV. Green Nanotechnology from Tea: Phytochemicals in Tea as Building Blocks for production of Biocompatible Gold Nanoparticles. *J. Mater. Chem.*, **2009**;19: 2912-2920
2. N. Chanda , R. Shukla , K. V. Katti , R. Kannan . Gastrin Releasing Protein Receptor -Specific Gold Nanorods: Breast and Prostate Tumor-avid Nanovectors for Molecular Imaging. *Nano Lett* **2009**;9: 1798-1805.
3. Fent GM, Casteel SW, Kim DY, Kannan R, Katti K, Chanda N, Katti K.V.; 2009, Biodistribution of maltose and gum arabic hybrid gold nanoparticles after intravenous injection in juvenile swine. *Nanomedicine*, **2009**, 5(2):128-35, PMID: 19480048.
4. Afrasiabi Z, Shukla R, Chanda N, Bhaskaran S, Upendran A, Zambre A, Katti KV, Kannan R. 2010, Nanoscale sensor design via in situ labeling of gold nanoparticles onto protein scaffolds. *J Nanosci Nanotechnol.* 2010, (2):719-25. PMID: 20352709.
5. Nripen Chanda, , Kattesh V. Katti, and Raghuraman Kannan et al; Bombesin Functionalized Gold Nanoparticles Show Cancer Receptor Specificity: Implications in Molecular Imaging and Therapy; Proceedings of the National Academy of Sciences (PNAS) – **2010**, (107):8760-8765. PMID: 20410458
6. Viator JA, Gupta S, Goldschmidt BS, Bhattacharyya K, Kannan R, Shukla R, Dale PS, Boote E, **Katti KV.**; Enhanced detection of circulating melanoma cells using gold nanoparticles as photoacoustic contrasting agents; *Progress in Biomedical Optics and Imaging - Proceedings of SPIE*, **2010**, vol. 7564,
7. Chanda N, Kan P, Watkinson LD, Shukla R, Zambre A, Carmack TL, Engelbrecht H, Lever JR, Katti K, Fent GM, Casteel SW, Smith CJ, Miller WH, Jurisson S, Boote E, Robertson JD, Cutler C, Dobrovolskaia M, Kannan R, Katti KV.; Radioactive gold nanoparticles in cancer therapy: therapeutic efficacy studies of (198)AuNP-GA nanoconstruct in prostate tumor-bearing mice. *Nanomedicine* 2010, (6):201-209. PMID: 19914401. (**Featured article on the journal's front page in April Issue**)
8. Boote E, Fent G, Kattumuri V, Casteel S, Katti K, Chanda N, Kannan R, Katti K, Churchill R. 2010, Gold nanoparticle contrast in a phantom and juvenile swine: models for molecular imaging of human organs using x-ray computed tomography. *Acad Radiol.* 2010, (4):410-7. PMID: 20207313.
9. Viator JA, Gupta S, Goldschmidt BS, Bhattacharyya K, Kannan R, Shukla R, Dale PS, Boote E, **Katti KV.** 2010, Detection of Gold Nanoparticle Enhanced Prostate Cancer Cells Using Photoacoustic Flowmetry with Optical Reflectance. 2010, *J. Biomed. Nanotech.* (6):1-5.
10. Viator, J.A., Gupta, S., Goldschmidt, B.S., Bhattacharyya, K., Kannan, R., Shukla, R., Dale, P.S., Boote, E., Katti, K. Detection of gold nanoparticle enhanced melanoma cancer cells using photoacoustic flowmetry: *Lasers in Surgery and Medicine*, 2011, 43, 333-338.
11. McCormack DR, Bhattacharyya K, Kannan R, **Katti KV**, Viator J A. Enhanced Photoacoustic Detection of Melanoma Cells Using Gold Nanoparticles. *Lasers in Surgery and Medicine*, 2011, 43, 333-338.
12. N. Chanda, R. Shukla, A. Zambre, S. Mekapothula, R. R. Kulkarni, K. Katti, K. Bhattacharyya, G. M. Fent, S. W. Casteel, E. J. Boote, J. A. Viator A. Upendran, R. Kannan, and **K. V. Katti**: An Effective Strategy for the Synthesis of Biocompatible Gold Nanoparticles Using Cinnamon Phytochemicals for Phantom CT Imaging and Photoacoustic Detection of Cancerous Cells; *Pharm Res.*, 2011, 28, 279-291.
13. Kannan R, Zambre, A, Chanda N, Kulkarni R, Cutler C, Shukla R, Katti K, Upendran R, **Katti KV.** Functionalized Radioactive Gold Nanoparticles in Tumor Therapy. *Wiley Interdisciplinary Reviews: Nanomedicine and Nanobiotechnology*, **2012**; vol. 4, no. 1, pp. 42–51,
14. Ravi Shukla , Nripen Chanda , Ajit Zambre , Anandhi Upendran , Kavita Katti , Cathy S Cutler , Charles Caldwell , Raghuraman Kannan , **Kattesh V Katti** and et.al; Laminin Receptor Specific Therapeutic Gold Nanoparticles (<sup>198</sup>AuNP-EGCg) Show Efficacy in Treating Prostate Cancer; Proceedings of the National

**BIOGRAPHICAL SKETCH**

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.  
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Liu, Jonathan T.C.		POSITION TITLE Assistant Professor of Biomedical Engineering	
eRA COMMONS USER NAME LIU.JONATHAN			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	YEAR(s)	FIELD OF STUDY
Princeton University	B.S.E.	1995-1999	Mechanical Engineering
Stanford University	M.S.	1999-2000	Mechanical Engineering
Stanford University	Ph.D.	2000-2005	Mechanical Engineering & Laser Diagnostics
Stanford University	Postdoctoral	2005-2009	Biomedical Optics & Molecular Imaging

**A. Personal Statement**

The molecular biophotonics lab develops custom microscopes and endoscopic imaging devices, along with molecularly targeted contrast agents, for diagnosing diseases and for guiding therapy. In particular, we have developed large-scale and miniature dual-axis confocal microscopes, as well as molecularly targeted contrast agents, to enable deep optical-sectioning microscopy of tissues for early detection and surgical guidance. We are also developing spectral-imaging endoscopes, in conjunction with Raman-coded nanoparticle probes, for multiplexed molecular imaging of disease biomarkers. These projects leverage Dr. Liu's multidisciplinary expertise in mechanical engineering, spectroscopy, biomedical optics, molecular imaging, instrumentation, and preclinical/clinical translation.

**B. Positions and Honors****Positions and Employment**

2010- Assistant Professor, Dept. of Biomedical Engineering, SUNY Stony Brook  
2009-2010 Instructor, Stanford University School of Medicine

**Other Experience and Professional Memberships**

2014 Ad hoc reviewer: NIH / NCI special emphasis panel, SBIR contracts  
2013 - 2014 Ad hoc reviewer: DSR study section, NIH / NIDCR special grants review committee  
2007-present Ad hoc reviewer: Journal of Biomedical Optics, Optics Letters, Optics Express, Biomedical Optics Express, Annals of Biomedical Engineering, IEEE Transactions of Biomedical Engineering, Journal of Visualized Experiments, Molecular Imaging and Biology, and PLOS ONE.  
2007 Ad hoc reviewer: NSF SBIR/STTR panel on imaging, Arlington, VA  
2005-present Member, Society of Photo-Optical Instrumentation Engineers (SPIE); Optical Society of America (OSA); Society for Molecular Imaging (SMI); Biomedical Engineering Society (BMES)

**Honors**

2013 BME department outstanding teacher award  
2009-2013 NIH K99/R00 "Pathway to Independence" Award (through the NIBIB)  
2009 Best Oral Presentation Award, Center for Biomedical Imaging at Stanford (CBIS) symposium  
2008 Gordon Research Conference on Lasers in Medicine and Biology: Travel Award and Panelist  
2008 World Molecular Imaging Congress (WMIC): Travel Award and Invited Speaker

- 2007 Nominated by Stanford University for the Burroughs Wellcome Fund (BWF) Career Award at the Scientific Interface (2007)
- 2006-2008 NIH Loan Repayment Award for clinical researchers
- 2005-2008 Canary Foundation / American Cancer Society postdoctoral fellowship for early cancer detection
- 2004 AIAA Best Paper by the Ground Testing Technical Committee
- 2003 AIAA Foundation Wright Brothers Graduate Award
- 2003 Outstanding Paper Award, AIAA Ground Testing Technical Committee
- 1999-2002 NSF Graduate Fellowship Award
- 1999 Tau Beta Pi, Princeton University
- 1999 Phi Beta Kappa, Princeton University
- 1999 Sigma Xi Book Award, Princeton University
- 1999 Sau-Hai Lam \*58 Prize as the top graduate in mechanical engineering, Princeton University

## C. Selected publications

### Peer-reviewed journals (selected)

1. Y. Wang, A. Khan, S.Y. Leigh, D. Wang, Y. Chen, D. Meza, and **J.T.C. Liu**, "Comprehensive spectral endoscopy of topically applied SERS nanoparticles in the rat esophagus," [manuscript under review].
2. S.Y. Leigh, Y. Chen, and **J.T.C. Liu**, "Modulated alignment dual-axis (MAD) confocal microscopy for deep optical sectioning in tissues," *Biomed. Opt. Exp.* (2014) [in press].
3. Y. Wang, A. Khan, M. Som; D. Wang, Y. Chen, S.Y. Leigh, D. Meza; P.Z. McVeigh, B.C. Wilson, and **J.T.C. Liu**, "Rapid ratiometric biomarker detection *in vivo* with topically applied SERS nanoparticles," *Technology* (2014) [in press].
4. **J.T.C. Liu**, D. Meza, and N. Sanai, "Trends in fluorescence image-guided surgery for gliomas," *Neurosurgery* (2014).
5. D. Wang, Y. Chen, Y. Wang, and **J.T.C. Liu**, "Comparison of line-scanned and point-scanned dual-axis confocal (DAC) microscope performance," *Opt. Lett.* 38, 5280-5283 (2013).
6. Y. Chen, and **J.T.C. Liu**, "Optimizing the performance of dual-axis confocal microscopes via Monte-Carlo scattering simulations and diffraction theory," *J. Biomed. Opt.*, 66006 (2013). [PMC3670619]
7. C. Zavaleta, E. Garai, **J.T.C. Liu**, S. Sensarn, M.J. Mandella, D. Van de Sompel, S. Friedland, J. Van Dam, C.H. Contag, and S.S. Gambhir, "A Raman-based endoscopic strategy for multiplexed molecular imaging," *Proc. Natl. Acad. Sci. U.S.A.*, (2013). [PMC3690865]
8. S.Y. Leigh, M. Som, and **J.T.C. Liu**, "Method for assessing the reliability of molecular diagnostics based on multiplexed Raman-coded nanoparticles," *PLoS ONE* 8, e62084 (2013). [PMC3631148]
9. D. Wang, S.Y. Leigh, Y. Chen, H. Haeberle, C.H. Contag, and **J.T.C. Liu**, "Microscopic delineation of medulloblastoma margins in a transgenic mouse model using a topically applied VEGFR-1 probe," *Transl. Oncol.* 5, 408-414 (2012). [PMC3542836] - *selected as cover article*
10. Y. Chen, D. Wang, and **J.T.C. Liu**, "Assessing the tissue-imaging performance of confocal microscope architectures via Monte-Carlo scattering simulations," *Opt. Lett.* 37, 4495-4497 (2012) [PMC3756678].
11. D. Wang, Y. Chen, and **J.T.C. Liu**, "A liquid optical phantom with tissue-like heterogeneities for confocal microscopy," *Biomed. Opt. Exp.* 12, 3153-3160 (2012). [PMC3521309]
12. S.Y. Leigh, N.O. Loewke, D. Wang, Y. Chen, and **J.T.C. Liu**, "Multi-color miniature dual-axis confocal microscope for *in vivo* point-of-care pathology," *Opt. Lett.* 37, 2430-2432 (2012). [PMC3804107]
13. H. Haeberle, J.T. Dudley, **J.T.C. Liu**, A. J. Butte, and C.H. Contag, "Identification of cell surface targets through meta-analysis of microarray data," *Neoplasia* 14, 666-669 (2012). [PMC3421962]
14. W. Piyawattanametha, H. Ra, Z. Qiu, S. Friedland, **J.T.C. Liu**, K. Loewke, G.S. Kino, O. Solgaard, T.D. Wang, M.J. Mandella, and C.H. Contag, "In vivo near-infrared dual-axis confocal microendoscopy in the human lower gastrointestinal tract," *J. Biomed. Opt.* 17, 021102 (2012). [PMC3380818]

## BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.  
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Robert F. Mattrey, M.D.	POSITION TITLE Professor of Radiology, Univ. of CA, San Diego
eRA COMMONS USER NAME (credential, e.g., agency login): mattrey	

EDUCATION/TRAINING (*Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.*)

INSTITUTION AND LOCATION	DEGREE (if applicable)	MM/YY	FIELD OF STUDY
State University of New York at Buffalo	B.S.	1971	Electrical Engineering
State University of New York at Buffalo	M.S.E.E.	1973	Electrical Engineering
State University of New York at Buffalo	M.D.	1978	Medicine
University of California, San Diego	Residency	1978–1981	Radiology
University of California, San Diego	Fellowship	1981–1982	CT/US/Interventional
Harvard School of Public Health	15 credit hrs	1997	MPH

### A. Personal Statement.

I am a clinician/scientist in Radiology with clinical expertise in Body Imaging including MRI, CT, and ultrasound and research expertise in contrast media and instrumentation with special interest in ultrasound. I have had the opportunity to translate contrast media for CT, MRI, and ultrasound imaging. I serve as the co-PI on a training grant in nanotechnology and I am the director of the 5-year Radiology Clinician-Scientist Program that is supported by a T32. I am also the Director of the Molecular imaging Program and as such I collaborate with many investigators in the School of Medicine and Campus on ultrasound and MRI projects. My technical background and interests have allowed me to direct my research efforts towards the interface between medicine and physical sciences. My motivation is to improve what we do to provide faster, cheaper, more accurate, efficient and convenient technologies to improve patient care.

### B. Positions and Honors.

#### Positions and Employment:

#### ***Academic Positions (University of California, San Diego, San Diego, CA, USA):***

1982–1988 Assistant Professor, Department of Radiology  
 1988–1991 Associate Professor, Department of Radiology  
 1991–2003 Professor of Radiology, Department of Radiology  
 2003–Pres. Professor, Department of Radiology

#### ***Research and Administrative Positions (University of California, San Diego, San Diego, CA, USA):***

1985–1990 Director, Magnetic Resonance Research  
 1985–2005 Chief, Body MRI Section, UCSD Medical Center  
 1990–Pres. Director, Five-Year Residency Program, Department of Radiology  
 1996–Pres. Vice Chairman & Director of Research, Department of Radiology  
 2001–Pres. Director, In vivo Cancer and Molecular Imaging Center, Moores UCSD Cancer Center

#### Honors and Awards:

1982 Association of University Radiologists, Memorial Award. **Mattrey RF**, Higgins CB. Detection of regional myocardial dysfunction during ischemia with computerized tomography: Documentation and physiologic basis. *Invest Radiol.* 1982; 17:329–335.

1984–1987 NCI Physician-Investigator Development Award Program (KO8-CA00940)

1988–1993 NCI Research Career Development Award (KO8-CA01319)

1990 Association of University Radiologists, Memorial Award. Coley BD, **Mattrey RF**, Mitten RM, Peterson T. The physiologic basis of the radiodense renal medulla after the administration of blood pool contrast agent, PFOB. *Invest Radiol.* 1990; 25:1287–1293.

1996 European and American Society of Uroradiology, First Place Award. **Mattrey RF**, Girard MS. Detection of partial renal infarction with ultrasound contrast agents.

- 2004 Association of University Radiologists, Herbert Stauffer Award. Lucidarme O, Nguyen T, Kono Y, Corbeil J, Choi SH, Varner J, **Mattrey RF**. Model for ultrasound contrast research: Exploratory study. *Acad Radiol*. 2004, 11:4–12.
- 2007 Association of University Radiologists Gold Medal Award
- 2007 International Contrast Media Research Harry Fisher Lifetime Achievement Award
- 2014 Society of Abdominal Radiology Lifetime Achievement Award

### **Professional Memberships:**

American Institute of Ultrasound in Medicine  
 Association of University Radiologists  
 Radiologic Society of North America  
 Society of Abdominal Radiology  
 Society of Magnetic Resonance in Medicine  
 Society of Molecular Imaging

### **C. Highly selected from over 125 Peer-reviewed publications (in chronological order).**

1. **Mattrey RF**, Scheible FW, Gosink BB, Leopold GR, Long DM, Higgins CB. Perfluorooctyl bromide: A liver/spleen-specific and a tumor-imaging ultrasound contrast material. *Radiology*. 1982; 145:759–762. (PMID: 7146409)
2. **Mattrey RF**, Strich G, Shelton RE, Gosink BB, Leopold GR, Lee T, Forsythe J. Perfluorochemicals as US contrast agents for tumor imaging and hepatosplenography: Preliminary clinical results. *Radiology*. 1987; 163:339–343. (PMID: 3550878)
3. Baker LL, Hajek PC, Burkhard TK, Dicapua L, Leopold GR, Hesselink JR, **Mattrey RF**. MR imaging of the scrotum: normal anatomy. *Radiology*, 1987; 163(1): p. 89-92. (PMID: 3823465)
4. Baker LL, Hajek PC, Burkhard TK, Dicapua L, Landa HM, Leopold GR, Hesselink JR, **Mattrey RF**. MR imaging of the scrotum: pathologic conditions. *Radiology*, 1987; 163(1): p. 93-8. (PMID: 3823466)
5. **Mattrey RF**, Hajek PC, Gylys-Morin VM, Baker LL, Martin J, Long DC, Long DM. Perfluorochemicals as gastrointestinal contrast agents for MR imaging: preliminary studies in rats and humans. *AJR Am J Roentgenol*, 1987; 148(6): p. 1259-63. (PMID: 3495156)
6. **Mattrey RF**, Trambert MA, Brown JJ, Young SW, Bruneton JN, Wesby GE, Balsara ZN. Perflubron as an oral contrast agent for MR imaging: Results of a phase III clinical trial. *Radiology*. 1994; 191: 841–848. (PMID: 8184076)
7. Kono Y, Lucidarme O, Choi SH, Rose SC, Hassanein TI, Alpert E, **Mattrey RF**. Contrast-enhanced Ultrasound as a Predictor of Treatment Efficacy within 2 Weeks after Transarterial Chemoembolization of Hepatocellular Carcinoma. *J Vasc Interv Radiol*. 2007; 18:57-65.
8. Simberg D, **Mattrey RF**. Targeting of perfluorocarbon microbubbles to selective populations of circulating blood cells. *Journal of drug targeting*. 2009, 17:392-8. (PMID: 19505207)
9. Girard OM, Du J, Agemy L, Sugahara KN, Kotamraju VR, Ruoslahti E, Bydder GM, **Mattrey RF**. Optimization of iron oxide nanoparticle detection using ultrashort echo time pulse sequences: Comparison of T(1), T(2) \*, and synergistic T(1) - T(2) \* contrast mechanisms. *Magn Reson Med* 2011; Jun; 65:1649-60. (PMID: 21305596) (Made Journal Cover)
10. Girard OM, Ramirez R, McCarty S, **Mattrey RF**. Toward absolute quantification of iron oxide nanoparticles as well as cell internalized fraction using multiparametric MRI. *Contrast Media Mol Imaging*, 2012; 7(4): p. 411-7. (PMID: 22649047)
11. Itani M, **Mattrey RF**. The Effect of Inhaled Gases on Ultrasound Contrast Agent Longevity In Vivo. *Mol Imaging Biol* 2012; 14: 40-6. (PMID: 21365328)
12. Nakatsuka MA, **Mattrey RF**, Esener SC, Cha JN, Goodwin AP. Aptamer-Crosslinked Microbubbles: Smart Contrast Agents for Thrombin-Activated Ultrasound Imaging. *Adv Mater*. 2012 Nov; 24 (45): 6010-6.
13. Newton IG, Plaisted WC, Messina-Graham S, Abrahamsson Schairer AE, Shih AY, Snyder EY, Jamieson CH, **Mattrey RF**. Optical imaging of progenitor cell homing to patient-derived tumors. *Contrast Media Mol Imaging*. 2012 Nov; 7 (6): 525-36 (PMID 22991319)
14. Cui, W, Tavri, S, Benchimol, MJ, Itani, M, Olson, ES, Zhang, H, Decyk, M, Ramirez, RG, Barback, CV, Kono, Y, **Mattrey, RF**. Neural progenitor cells labeling with microbubble contrast agent for ultrasound imaging in vivo. *Biomaterials*, 2013; 34: 4926-35. (PMID: 23578557)
15. Olson ES, Orozco J, Wu CZ, Malone CD, Yi BH, Gao W, Eghtedari M, Wang J, **Mattrey RF**. Toward in vivo Detection of Hydrogen Peroxide with Ultrasound Molecular Imaging. *Biomaterials*, 2013; 34(35): p. 8918-24. (PMID: 23958028)

## BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2.

Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Mitchell, Duane Anthony, M.D., Ph.D. <hr/> eRA COMMONS USER NAME (credential, e.g., agency login) mitch016	POSITION TITLE Phyllis Kottler Friedman Professor in Neurosurgery Associate Professor of Neuroscience, Pathology, Immunology, and Laboratory Medicine		
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	MM/YY	FIELD OF STUDY
Rutgers College, New Brunswick, N.J. Duke University Medical School, Durham, N.C. Duke University Graduate School, Durham, N.C.	B.A. M.D. Ph.D.	May, 1993 May, 2001 May, 2001	Biological Sciences Medicine Immunology

### A. Personal Statement

**Duane A. Mitchell, M.D., Ph.D.** is the Phyllis Kottler Friedman Professor of Neurosurgery, University of Florida Endowed Cancer Research Chair and the Director of University of Florida Brain Tumor Immunotherapy Program (UFBTIP). He also functions as Co-Director of the Preston A. Wells, Jr. Center for Brain Tumor Therapy in collaboration with Dr. William Friedman, Chair of Neurosurgery. Dr. Mitchell was recently recruited from Duke University where he served as Director of Preclinical Research within the Preston Robert Tisch Brain Tumor Center at Duke and Associate Director of the Duke Brain Tumor Immunotherapy Program. His recruitment was made possible by a \$20 million investment in the expansion of the brain tumor center at University of Florida, and Dr. Mitchell and his team of researchers have established a comprehensive translational neuro-oncology program. He has extensive translational research experience involving the immunologic treatment of cancer, having served as Principal Investigator on seven FDA-approved Phase I/II clinical trials involving pediatric and adult patients with malignant brain tumors. His expertise in translational research has been sought out nationally as an advisor to the National Cancer Institute's Alliance for Nanotechnology in Cancer, as an External Advisory Board member for the California Institute of Regenerative Medicine, as an appointed member of the Immunotherapy Subcommittee for the NCI Brain Malignancy Steering Committee, and as Chair of NCI Pediatric Brain Tumor Consortium (PBTC) Immunotherapy Committee. Dr. Mitchell is primary inventor and co-inventor on a number of issued and pending patent applications related to the immunologic treatment of brain cancer and a leader of many pioneering and innovative research programs. His current research focus is on adoptive cellular therapy and RNA-based nanoparticle vaccines targeting pediatric and adult brain tumors. He currently serves as a permanent member on NIH study section (Cancer Immunotherapy and Immunopathology) and has served as an ad hoc study section reviewer and special emphasis panel study section member on several NIH review boards, as well as reviewer for several international grant review boards.

### B. Positions and Honors

#### Positions and Employment

1993-2001	Medical Scientist Training Program (MD/PhD) Candidate, Duke University
2001-2003	Resident (Pathology), Duke University Medical Center
2003-2005	Research Associate, Duke University Medical Center
2005-2013	Assistant Professor of Surgery (Neurosurgery)
2008-2013	Director of Preclinical Research, Preston Robert Tisch Brain Tumor Center at Duke
2008-2013	Associate Director, Duke Brain Tumor Immunotherapy Program

2013-present Associate Professor of Neurosurgery and Neuroscience, University of Florida  
 2013-present Co-Director, Preston A. Wells, Jr. Center for Brain Tumor Therapy at University of Florida  
 2013-present Director, University of Florida Brain Tumor Immunotherapy Program  
 2013-present University of Florida Endowed Cancer Research Chair  
 2013-present Phyllis Kottler Professor (Department of Neurosurgery)

### **Other Experience and Professional Memberships**

2006-2010 Principal Investigator, Phase I/II Clinical Trial: "Anti-Tumor Immunotherapy Targeted Against Cytomegalovirus in Patients with Newly Diagnosed Glioblastoma Multiforme during Recovery from Therapeutic Temozolomide-induced Lymphopenia". (ATTAC Trial: FDA-IND-BB-12839)  
 2007-2010 Principal Investigator, Phase I Clinical Trial: "REGULATory T-Cell Inhibition with Daclizumab (Zenapax®) during Recovery from Therapeutic Temozolomide-induced Lymphopenia during Antitumor Immunotherapy Targeted against *Cytomegalovirus* in Patients with Newly-Diagnosed Glioblastoma Multiforme". (REGULATe Trial: FDA-IND-BB-12839)  
 2008-2013 Member, Duke University Institutional Review Board  
 2008-present Principal Investigator, Phase I Clinical Trial: "Recurrent GBM Stem cell Tumor Amplified RNA Immunotherapy Trial". (RE-START: FDA-IND-BB-13630)  
 2008-present Principal Investigator, Phase I/II Clinical Trial: "Evaluation of Recovery from Drug-Induced lymphopenia using T-Cell Adoptive Transfer". (ERADICATe Trial: FDA-IND-BB-13240)  
 2009-present Principal Investigator, Phase I/II Clinical Trial: "Recurrent Medulloblastoma and Primitive Neuroectodermal Tumor Adoptive T Cell Therapy during Recovery from Myeloablative Chemotherapy and Hematopoietic Stem Cell Transplantation". (Re-MATCH Trial: FDA IND-BB-14058)  
 2009-2011 Consultant, NCI Alliance on Nanotechnology in Cancer  
 2011-2013 Member, Duke Cancer Institute Office of Health Equity Advisory Council  
 2011-present Member, External Advisory Board, California Institute of Regenerative Medicine, City of Hope Medical Center  
 2012-2013 Member, Professionalism Council, Duke University Medical Center  
 2012-2013 Member, Duke Cancer Institute Safety and Oversight Committee  
 2012-present Chair, Pediatric Brain Tumor Consortium Immunotherapy Committee  
 2013-present Member, NCI Brain Malignancy Steering Committee Immunotherapy Working Group  
 2013-2019 Member, Cancer Immunopathology and Immunotherapy NIH Study Section

### **Honors and Awards**

1989-1993 James Dickson Carr Scholar  
 1993 Henry Rutgers Honors Scholar  
 1993-2001 Medical Scientist Training Program (MD/PhD) grant recipient  
 2001 Association of Pathology Chairs Honor Society  
 2003 Duke Comprehensive Cancer Center Research Award  
 2003 ABCC Young Investigators' Award  
 2004 Billy Grey Chair of Research Award (The Brain Tumor Society)  
 2005 Brain Cancer SPORE Career Development Award  
 2007 Billy Grey Chair of Research Award (The Brain Tumor Society)  
 2007 ABCC Developmental Research Award

### **Selected peer-reviewed publications in chronological order**

1. Nair SK, De Leon G, Boczkowski D, Schmittling R, Xie W, Staats J, Liu R, Johnson LA, Weinhold K, Arche GER, Sampson JH, **Mitchell DA**. Recognition and killing of autologous, primary glioblastoma tumor cells by human cytomegalovirus pp65-specific cytotoxic T cells. Clin Can Res epub March 2014.
2. Choi BD, Gedeon PC, Herndon JE 2nd, Archer GE, Reap EA, Sanchez-Perez L, **Mitchell DA**, Bigner DD, Sampson JH. Human regulatory T cells kill tumor cells through granzyme-dependent cytotoxicity upon retargeting with a bispecific antibody. Can Immunol Res. 2013;1(3):163. PMID: 24570975



### BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.  
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Shimon Weiss	POSITION TITLE Professor of Chemistry and Biochemistry		
eRA COMMONS USER NAME (credential, e.g., agency login) weiss22	Professor of Physiology		
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	MM/YY	FIELD OF STUDY
Technion, Haifa, Israel Institute of Technology	B.Sc.	07/1984	Electrical Engineering
Technion, Haifa, Israel Institute of Technology	D.Sc	11/1989	Electrical Engineering

#### A. Personal Statement

My lab has been working on ultrasensitive single molecule spectroscopy and imaging methods, and on the development of quantum dots as probes for molecular imaging. Our work on quantum dots (QDs) has led to the founding of Quantum Dot Corporation (later acquired by Invitrogen Inc., now Life Technologies). In recent years my team has continued to develop QDs technologies such as novel peptide-coating technology, unique conjugation chemistries and various approaches for specific targeting of QDs to cellular proteins. My lab has also developed a novel superresolution imaging method dubbed SOFI and a variety of novel detectors for advanced, high throughput, single molecule spectroscopy and imaging. More recently, we developed and measured voltage sensing nanorods (vsNRs). My unique background in solid state physics, biology, and chemistry uniquely qualifies me to perform the work proposed here.

#### B. Positions and Honors

##### Positions and Employment

1989-1990	Postdoc	AT&T Bell Laboratories
1990-2001	Staff Scientist	Materials Sciences Division, LBNL
1998	Founding Scientist	Quantum Dot Corporation, Hayward, CA
1998-2001	Staff Scientist	Physical BioSciences Division, LBNL
1998-2002	Scientific Advisory Board	Quantum Dot Corporation, Hayward, CA
2001-to date	Professor of Chemistry & Biochemistry	UCLA
2001-to date	Professor of Physiology	UCLA
2001-	Full Member	California Nanosystems Institute, UCLA
2002-	Full Member	Molecular Biology Institute, UCLA
2002-	SAB	Molecular Foundry, LBNL
2003-	Visiting Professor	EECS, Technion ; Chemistry, Weizmann Inst.
2005-2008	SAB	Lawrence Livermore National Laboratory, Livermore, CA
2007-	SAB	BioQuant, ViroQuant, CellNetworks, University of Heidelberg
2008-2011	Consultant	Lifetech (Invitrogen) Corp.
2011-to date	Editorial board	Optical Nanoscopy

##### Honors

Rothschild Fellowship for post-docs, 1989/1990; Outstanding Performance Award, Lawrence Berkeley National Laboratory, 1993; Fellow of the Optical Society of America, 1999; The Michael and Kate Barany Biophysical Society Award, 2001; 2006 Rank Prize, Royal College of Physicians, London; The Erna and Jakob Michael

Program Director/Principal Investigator (Last, First, Middle): Weiss, Shimon

Visiting Professor, Weizmann Institute of Science; The Dean Willard Chair in Chemistry and Biochemistry, 2009; The Humboldt Research Award, 2012.

**C. Selected Peer-reviewed Publications** (Selected from 142 peer-reviewed publications; 28 issued & 26 pending patents)

**Most relevant to the current application**

1. Park, K.; Deutsch, Z.; Li, J.J.; Oron, D.; Weiss, S.; "Single Molecule Quantum Confined Stark Effect Measurements of Semiconductor Nanoparticles at Room Temperature", *ACS Nano*, **2012**, 6, 10013–10023. PMID:PMC3507316.
2. Michalet, X., Pinaud, F.F., Bentolila, L.A., Tsay, J.M., Doose, S., Li, J.J., Sundaresan, G., Wu, A.M., Gambhir, S.S. & Weiss, S. Quantum dots for live cells and in vivo imaging and diagnostics. *Science*, **2005**, 307, 538-44. PMID: 15681376 PMID: PMC1201471
3. Pinaud, F.; King, D.; Moore, H. P.; Weiss, S., Bioactivation and Cell Targeting of Semiconductor CdSe/ZnS Nanocrystals with Phytochelatin-related Peptides. *J. Am. Chem. Soc.* **2004**, 126, 6115-6123. PMID:15137777
4. Schipper, M.L., Iyer, G., Koh, A.L., Cheng, Z., Ebenstein, Y., Aharoni, A., Keren, S., Bentolila, L.A., Li, J., Rao, J., Chen, X., Banin, U., Wu, A.M., Sinclair, R., Weiss, S., Gambhir, S.S., "Particle Size, Surface Coating, and Pegylation Influence the Biodistribution of Quantum Dots in Living Mice", *Small*, **2009**, 5, 126–34; PMID: 19051182 PMID: PMC3084659
5. Iyer, G.; Michalet, X.; Pinaud, F.F.; Matyas, C.E.; Chang, Y.P.; Payne, G.; Weiss, S.; "High Affinity scFv-hapten Pair as a Tool for Quantum Dot Labeling and Tracking of Single Proteins in Live Cells", *Nano Lett.*, **2008**, 8, 4618-23; PMID:19053789 PMID:PMC3084663

**Additional recent publications of importance to the field (in chronological order)**

1. Bruchez, M., Jr., Moronne, M., Gin, P., Weiss, S. & Alivisatos, A.P. Semiconductor nanocrystals as fluorescent biological labels. *Science*, **1998**, 281, 2013-6. PMID: 9748157.
2. Ha, T.; Ting, A. Y.; Liang, J.; Caldwell, W. B.; Deniz, A. A.; Chemla, D. S.; Schultz, P. G.; Weiss, S., Single-molecule fluorescence spectroscopy of enzyme conformational dynamics and cleavage mechanism. *Proc Natl Acad Sci U S A* **1999**, 96, (3), 893-8. PMID: 9927664 PMID: PMC 15321
3. Weiss, S., Fluorescence spectroscopy of single biomolecules. *Science* **1999**, 283, (5408), 1676-83.
4. Weiss, S., Measuring conformational dynamics of biomolecules by single molecule fluorescence spectroscopy. *Nat Struct Biol* **2000**,7,(9), 724-9, PMID: 10966638.
5. Schipper, M.L.; Cheng, Z.; Lee, S.W.; Keren, S.; Bentolila, L.A.; Sundaresan, G.; Iyer, G.; Gheysens, O.; Ebenstein, Y.; Li, J.; Rao, J.; Chen, X.; Wu, A.M.; Weiss, S.; Gambhir, S.S.; "MicroPET-Based Biodistribution of Quantum Dots in Living Mice", *J. of Nuclear Medicine*, **2007**; 48, 1511-1518. PMID: PMC2299220
6. Li, J.J.; Tsay, J.; Michalet, X.; Weiss, S., "Wave-function engineering: from quantum wells to near-infrared type-II colloidal quantum dots synthesized by layer-by-layer colloidal epitaxy", *Chemical Physics*, **2005**, 318, 82–90.
7. Dertinger, T.; Colyer, R.; Iyer, G.; Weiss, S.; Enderlein, J.; "Fast, background-free, 3D superresolution optical fluctuation imaging (SOFI)", *Proc Natl Acad Sci*, **2009**, 106, 22287-92, PMID:20018714 PMID:PMC 2799731
8. Iyer, G.; Pinaud, F.; Xu, J.; Ebenstein, Y.; Li, J.; Dahan, M.; Weiss, S.; "Aromatic Aldehyde and Hydrazine Activated Peptide Coated Quantum Dots for Easy Bioconjugation and Live Cell Imaging", *Bioconjugation Chemistry*, **2011**, 22, 1006–1011. PMID: 21553893, PMID: PMC3116077.
9. Xu, J.; Ruchala, P.; Ebenstein, Y.; Li, J.J.; Weiss, S.; "Stable, compact, and bright biofunctional Quantum Dots with improved peptide coating", *J. Phys. Chem. B*, **2012**, 116, 11370–11378. PMID:22920542 PMID:PMC3470653
10. Ebenstein, Y.; Gassman, N.R.; Antelman, J.; Kim, Y.; Kim, S.; Ho, S.O.; Samuel, R.; Michalet, X.; Weiss, S.; "Lighting up Individual DNA Binding Proteins with Quantum Dots", *Nano Lett.*, **2009**, 9, 1598–1603. PMID:1920670 PMID: PMC 3084662

**BIOGRAPHICAL SKETCH**

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.  
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Wu, Anna M.		POSITION TITLE Professor , Molecular & Medical Pharmacology Professor, Pathology & Laboratory Medicine	
eRA COMMONS USER NAME (credential, e.g., agency login) WUAM22			
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)			
INSTITUTION AND LOCATION	DEGREE (if applicable)	MM/YY	FIELD OF STUDY
Harvard University, Cambridge, MA	BA	06/75	Biochemistry
Yale University, New Haven, CT	PhD	12/79	Mol. Biophys. Biochem.
Yale University, New Haven, CT	Postdoc	06/82	Mol. Bio. & Hum. Gen.
University of California, San Francisco, CA	Postdoc	06/84	Biochem. & Biophys.

**A. Positions and Honors****Positions and Employment**

1984-1995 Assistant Research Scientist, Dept. of Molecular Biochemistry, Beckman Res. Inst. of the City of Hope, Duarte, CA.  
 1995-2000 Assoc. Res. Sci., Dept. of Molecular Biology, Beckman Res. Inst. of the City of Hope  
 1998-1999 Visiting Associate Professor, Crump Institute for Biological Imaging, Dept. of Molecular and Medical Pharmacology, UCLA School of Medicine, Los Angeles, CA (sabbatical)  
 2000-2002 Associate Professor of Molecular Biology, Beckman Res. Inst. of the City of Hope, Duarte, CA  
 2002-2006 Associate Professor, Crump Institute for Molecular Imaging, Dept. of Molecular and Medical Pharmacology, Geffen School of Medicine at UCLA, Los Angeles, CA  
 2003- Member, Jonsson Comprehensive Cancer Center, Geffen School of Medicine at UCLA;  
 Director, Cancer Molecular Imaging Program (2006 - present)  
 2006- Professor, Dept. of Molecular and Medical Pharmacology, Geffen School of Medicine at UCLA  
 2007- Professor, Dept. of Pathology and Laboratory Medicine, Geffen School of Medicine at UCLA  
 2009- Member, California Nanosystems Institute, UCLA, Los Angeles, CA  
 2012 - Vice Chair, Dept. of Molecular and Medical Pharmacology, Geffen School of Medicine at UCLA

**Other Experience and Professional Memberships**

2001- Associate Editor, *Molecular Imaging and Biology*  
 2004- Editorial Advisory Board, *Bioconjugate Chemistry*  
 2007- Editorial Board, *Protein Engineering Design & Selection*  
 2008- Editorial Board, *Cancer Biotherapy & Radiopharmaceuticals*

1990-1991 Grant review panel, American Heart Assn. L.A. Affiliate  
 1994, 1997 Grant review panels, US Army Breast Cancer Research Program (Molecular Biology, Genetics)  
 2000,2001 Grant review panels, US Department of Energy (Nuclear Medicine, Targeted Cell Therapy)  
 2000-2003 California Breast Cancer Research Council; elected Council Chair, 2002-2003  
 2003- Grant review panels, National Institutes of Health (ad hoc, various, including Program Project grants, ICMIC, Bioengineering Research Partnerships, ARRA, SBIR, and other Special Emphasis Panels)  
 2006 Department of Defense Breast Cancer Research Program Integration Panel (ad hoc)  
 2007-2009 NIH MEDI-A review panel (ad hoc)  
 2009-2012 NIH CMIP review panel (Clinical Molecular Imaging and Probe Development)  
 2009- Interfaces study section member, Cancer Research and Prevention Institute of Texas  
 2012-2013 President-Elect, World Molecular Imaging Society

2013- President, World Molecular Imaging Society

### Honors

1970 Brown-Hazen Summer Fellowship,  
1974 Dreyfus Foundation Summer Fellowship  
1982-1984 Leukemia Society Special Fellowship,  
1997 Teaching Award, Project LEAD, National Breast Cancer Coalition

### **B. Selected peer-reviewed publications (past five years)**

1. Kenanova, V.E., Barat, B., Olafsen, T., Chatziioannou, A., Herschman, H.R., Braun, J., and Wu, A.M. (2009) Recombinant carcinoembryonic antigen as a reporter gene for molecular imaging. *Eur. J. Nucl. Med. Molec. Imag.* 36:104-114.
2. Wu, A.M. (2009) Antibodies and Antimatter: The resurgence of immunoPET. *J. Nuc. Med.* 50:2-5.
3. Schipper, M.L., Iyer, G., Koh, A.L., Cheng, Z., Ebenstein, Y., Ahroni, A., Keren, S., Bentolilla, L., Li, J., Rao, J., Chen, X., Banin, U., Wu, A.M., Sinclair, R., Weiss, S., and Gambhir, S.S. (2009) Particle size, surface coating, and PEGylation influence the biodistribution of quantum dots in living mice. *Small*, 5:126-134.
4. Olafsen, T., Betting, D., Kenanova, V.E., Raubitschek, A.A., Timmerman, J.M. and Wu, A.M. (2009) Recombinant anti-CD20 antibody fragments for small-animal PET imaging of B-cell lymphoma xenografts, *J. Nucl. Med.*, 50:1500-1508.
5. Vaidyanathan, G., Jestin, E., Olafsen, T., Wu, A.M. and Zalutsky, M. Evaluation of an anti-p185<sup>HER2</sup> (scFv-C<sub>H</sub>2-C<sub>H</sub>3)<sub>2</sub> fragment following radioiodination using two different residualizing labels: SGMIB and IB-Mal-D-GEEK. (2009) *Nucl. Med. Biol.* 36:671-680.
6. Barat, B., Sirk, S., McCabe, K., Li, J., Koh, A.L., Lepin, E., Olafsen, T., Gambhir, S.S., Weiss, S., and Wu, A.M. (2009) Cys-diabody quantum dot conjugates (immunoQdots) for cancer marker detection, *Bioconj. Chem.* 20:1474-1481.
7. Afshar, S., Olafsen, T., Wu, A.M., and Morrison, S.L. (2009) Characterization of an engineered human purine nucleoside phosphorylase fused to an anti-HER2/neu single chain Fv for use in ADEPT. *J. Exp. Clin. Canc. Res.* 28:147.
8. Frank, R., Edmiston, M., Kendall, S.E., Najbauer, J., Cheung, C.-W., Kassa, T., Metz, M.Z., Kim, S.U., Glackin, C., Wu, A.M., Yazaki, P.J., and Aboody, K. (2009) Neural stem cells as a novel platform for tumor-specific delivery of therapeutic antibodies. *PLoS ONE*, 4:e8314.
9. Olafsen, T., Sirk, S., Betting, D., Kenanova, V.E., Bauer, K., Ladno, W., Raubitschek, A.A., Timmerman, J.M., and Wu, A.M. (2010) ImmunoPET imaging of B-cell lymphoma using <sup>124</sup>I-anti-CD20 scFv dimers (diabodies). *Prot. Eng. Des. Sel.*, 23:243-249.
10. Olafsen, T. and Wu, A.M. (2010) Antibody vectors for imaging. *Seminars in Nuclear Medicine* 40:167-181.
11. Lepin, E.J., Leyton, J.V., Zhou, Y., Olafsen, T., Hahm, S., Marks, J.D., Reiter, R.E., and Wu, A.M. (2010) An affinity matured minibody for PET imaging of prostate stem cell antigen (PSCA)-expressing tumors. *Eur. J. Nucl. Med. Mol. Imaging.*, 37:1529-1538.
12. McCabe, K.E. and Wu, A.M. (2010) Positive Progress in ImmunoPET – Not Just a Coincidence. *Cancer Biother. Radiopharm.* 25:253-261.
13. Wong, J.Y.C., Somlo, G., Yamauchi, D., Williams, L.E., Wu, A.M., Yazaki, P.J., Shively, J.E., Colcher, D., and Raubitschek, A. (2010) A pretherapy biodistribution and dosimetry study of Indium-111 radiolabeled trastuzumab in patients with HER2 overexpressing breast cancer. *Canc. Biother. Radiopharm.* 25:387-394.
14. Barat, B., Kenanova, V., Olafsen, T., and Wu, A.M. (2011) Evaluation of two internalizing carcinoembryonic antigen reporter genes for molecular imaging. *Mol. Imag. Biol.* 13:526-535.
15. Kenanova, V.E., Olafsen, T., Salazar, F., Knowles, S., Williams, L.E., and Wu, A.M. (2010) Tuning the serum persistence of human serum albumin domain III fusion proteins. *Prot. Eng. Des. Sel.* 23:789-798.
16. Olafsen, T., Young, S.G., Davies, B.S.J., Kenanova, V.E., Voss, C., Young, G., Wong, K.-P., Barnes, R.H., Tu, Y., Weinstein, M.M., Nobumori, C., Huang, S.-C., Goldberg, I.J., Bensadoun, A., Wu, A.M., and Fong, L.G. (2010) Unexpected expression pattern for glycosylphosphatidylinositol-anchored HDL-binding protein

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## BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2. Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

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NAME Zinn, Kurt R.	POSITION TITLE Professor of Radiology, Medicine, Pathology, Surgery, Computer & Elect. Engineering, Director, Div. of Advanced Medical Imaging Research		
eRA COMMONS USER NAME (credential, e.g., agency login) KurtZinn			
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)			
INSTITUTION AND LOCATION	DEGREE (if applicable)	MM/YY	FIELD OF STUDY
University of Missouri-Columbia	BA	05/81	Chemistry
University of Missouri-Columbia	DVM	05/86	Veterinary Medicine
University of Missouri-Columbia	MS	12/86	Chemistry
University of Missouri-Columbia	PhD	12/92	Biochemistry

### A. Personal Statement

I am trained in radiochemistry, biochemistry, animal models of disease, molecular biology, and imaging. My original degrees were in chemistry (B.A., M.S.), biochemistry (Ph.D.), and veterinary medicine (D.V.M.). The formal training was enhanced by 9 years of experience with radioisotope production and development of imaging instrumentation at the University of Missouri. Since arrival at UAB in 1995, I have focused my full effort on the application of molecular imaging in animal models. I have developed new genetic reporters for imaging gene transfer, and established new approaches for imaging signal transduction, cell trafficking, and cancer therapy. The imaging approaches are translational in nature. For example, the hSSTR2 for imaging gene transfer was included in a phase I study for ovarian cancer therapy with an adenoviral vector (R. Alvarez, PI; published 2012 Clin Can Res), and phase II studies with the death receptor agonist (TRA8) for breast cancer included MR DWI and perfusion approaches (A. Forero, PI) that were demonstrated to predict response in preclinical studies by my group. Currently I am part of "Phase I Trial of Intraperitoneal Pb-212-TCMC-Trastuzumab for HER-2 Expressing Malignancy (NCT01384253, PI:Meredith)" and serve as quality assurance director for cGMP drug production. Preclinical studies in collaboration with Dr. Eben Rosenthal have enabled an approved IND (#115706) with the FDA in September 2013 to evaluate fluorescence imaging to improve surgical resection of head and neck cancer in the operating room, and the phase I trial is under way.

### B. Positions and Honors

#### Positions and Employment

1986–1993	Research Scientist (University of Missouri)
1993-1995	Senior Research Scientist (University of Missouri)
1995–2000	Assistant Professor (UAB), Radiology
2000-2003	Associate Professor with tenure (UAB), Radiology
2001–2006	Co-Director, Laboratory for Multi-Modality Imaging Assessment (UAB)
2009	Visiting Professor at Stanford (research sabbatical)
2003-	Professor with tenure (UAB), Radiology, Medicine, Pathology, and Nutrition Sciences
2007-	Director, Laboratory for Multi-Modality Imaging Assessment (UAB)
2009-	Director, Division of Advanced Medical Imaging Research; Department of Radiology
2011-	Professor, Department of Computer and Electrical Engineering

#### Other Experience and Professional Memberships

1998-2009	Member, American Society for Gene Therapy
2001-2004	Ad-Hoc Member, Radiology Study Section and P50 Special Emphasis Panels
2004-2005	Chair, Institute for Molecular Imaging, Academy of Molecular Imaging
2009-11	Chair, Education Task Force, Society of Nuclear Medicine
2009-12	Member, Interfaces Review Committee, for the Cancer Prevention and Research Institute of Texas (CPRIT)

- 1990- Member, Society of Nuclear Medicine  
2003- Member, Academy of Molecular Imaging, Now World Molecular Imaging Society

### **Honors**

1987 Phi Lambda Upsilon; 1988 Sigma Xi; 1989 Outstanding Graduate Student Teaching Award; 1996 Benedict Cassen Imaging Award; 1997 Southern Societies Young Faculty Award; 1997 Benedict Cassen Imaging Award; Patents: 1992 U.S. Patent # 5,154,897 for Method and Apparatus for the Generation of Radioisotopes; 1995 U.S. Patent #5,409,677 for Process for Separating a Radionuclide from Solution; 1995 U.S. Patent #5,403,573 for Radiolabeled Protein Composition and Method for Radiation Synovectomy.

### **C. Selected Peer-reviewed Publications** (Selected from 133 peer-reviewed publications)

#### **Most relevant to the current application**

1. Frank SJ, Wang X, He K, Yang N, Fang P, Rosenfeld RG, Hwa V, Chaudhuri TR, Deng L, **Zinn KR**. In Vivo Imaging of Hepatic Growth Hormone Signaling. *Mol Endo* 20(11): 2819-30, 2006.
2. Wang X, Jiang J, Warram J, Baumann G, Gan Y, Menon RK, Denson LA, **Zinn KR**, and Frank SJ. Endotoxin-Induced Proteolytic Reduction in Hepatic Growth Hormone (GH) Receptor: A Novel Mechanism for GH Insensitivity. *Mol Endocrinol* 22(6): 1427-37, 2008. [pmcid:2422827]
3. Chewning JH, Dugger KJ, Chaudhuri TR, **Zinn KR**, Weaver CT. Bioluminescence-based visualization of CD4 T cell dynamics using a T lineage-specific luciferase transgenic model. *BMC Immunol* 10:44, 2009. [pmcid:2736162]
4. Day KE, Beck LN, Deep NL, Kovar J, **Zinn KR**, Rosenthal EL. Fluorescently labeled therapeutic antibodies for detection of microscopic melanoma. *Laryngoscope*. 2013 Apr 24. doi: 10.1002/lary.24102. [Epub ahead of print] PMID: 23616260
5. Heath CH, Deep NL, Beck LN, Day KE, Sweeny L, **Zinn KR**, Huang CC, Rosenthal EL. Use of panitumumab-IRDye800 to image cutaneous head and neck cancer in mice. *Otolaryngol Head Neck Surg*. 2013 Jun;148(6):982-90. doi: 10.1177/0194599813482290. Epub 2013 Mar 22. PMID: 23525846

#### **Additional recent publications of importance to the field (in chronological order)**

1. **Zinn KR**, Chaudhuri TR, Szafran AA, O'Quinn D, Weaver C, Dugger K, Lamar D, Kesterson RA, Wang X, Frank SJ. Noninvasive bioluminescence imaging in small animals. *ILAR J* 49 (1): 103-15, 2008. (PMCID:18172337)
2. Kim H, Morgan DE, Zeng H, Grizzle WE, Warram JM, Stockard CR, Wang D, **Zinn KR**. Breast Tumor Xenografts: Diffusion-weighted MR Imaging to Assess Early Therapy with Novel Apoptosis-Inducing Anti-DR5 Antibody. *Radiology* 248(3): 844-851, 2008. [pmcid:2657851].
3. Matthews K, Noker PE, Tian B, Grimes SD, Fulton R, Schweikart K, Harris R, Aurigemma R, Wang M, Barnes MN, Siegal GP, Hemminki A, **Zinn K**, Curiel DT, Alvarez RD. Identifying the safety profile of Ad5.SSTR/TK.RGD, a novel infectivity-enhanced bicistronic adenovirus, in anticipation of a phase I clinical trial in patients with recurrent ovarian cancer. *Clin Cancer Res* 15(12):4131-7, 2009.
4. Khotaskaya YB, Dai Y, Ritchie JP, Macleod V, Yang Y, **Zinn K**, Sanderson RD. Syndecan-1 is required for robust growth, vascularization and metastasis of myeloma tumors in vivo. *J Biol Chem* 284(38):26085-95, 2009. (PMCID:1956856)
5. Borovjagin AV, McNally LR, Wang M, Curiel DT, MacDougall MJ, and **Zinn KR**, Noninvasive Monitoring of mRFP1- and mCherry-Labeled Oncolytic Adenoviruses in an Orthotopic Breast Cancer Model by Spectral Imaging. *Mol Imag* 9: 59-75, 2010.
6. Beck BH, Kim HG, Kim H, Samuel S, Liu Z, Shrestha R, Haines H, **Zinn K**, Lopez RD. Adoptively transferred ex vivo expanded gammadelta-T cells mediate in vivo antitumor activity in preclinical mouse models of breast cancer. *Breast Cancer Res Treat*, 122(1):135-144, 2010. (PMCID:19763820)
7. Jiang J, Wan Y, Wang X, Xu J, Harris JM, Lobie PE, Zhang Y, **Zinn KR**, Waters MJ, Frank SJ. Inhibitory GH receptor extracellular domain monoclonal antibodies: three-dimensional epitope mapping. *Endocrinology*. 152(12): 4777-88, 2011.
8. Turk AN, Byer SJ, **Zinn KR**, Carroll SL. Orthotopic Xenografting of Human Luciferase-Tagged Malignant Peripheral Nerve Sheath Tumor Cells for *in vivo* Testing of Candidate Therapeutic Agents. *J Vis Exp* (49), 2011. [pmcid:PMC3197311]
9. Shah N, Zhai G, Knowles JA, Stockard CR, Grizzle WE, Fineberg N, Zhou T, **Zinn KR**, Rosenthal EL, Kim H. <sup>18</sup>F-FDG PET/CT Imaging Detects Therapy Efficacy of Anti-EMMPRIN Antibody and Gemcitabine in

Translational Cancer Research  
Richard O'Reilly, M.D., Chair

Peer Review Panel Members for Approval

1. Stephen Baylin, M.D.
2. Riccardo Dalla-Favera, M.D.
3. John DiPersio, M.D., Ph.D.
4. Stephan Grupp, Ph.D.
5. Robertson Parkman, M.D.
6. Simon Powell, Ph.D.
7. Jerome Ritz, M.D.
8. Alessandro Sette, D.Sc.

## BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2.  
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME <b>Baylin, Stephen B</b> eRA COMMONS USER NAME (credential, e.g., agency login) <b>sbaylin1</b>	POSITION TITLE <b>Professor</b>		
EDUCATION/TRAINING ( <i>Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.</i> )			
INSTITUTION AND LOCATION	DEGREE	YYYY	FIELD OF STUDY
Duke University, Durham, NC	B.A.	1964	Psychology
Duke University Medical School, Durham, NC	M.D.	1968	Medicine
Duke University Medical School, Durham, NC	Intern/Res	1969	Internal Medicine
The Johns Hopkins Hospital, Baltimore, MD	Asst	1972	Internal Medicine
The Johns Hopkins Univ, SOM, Baltimore, MD	Fellow	1974	Endocrinology, Psych

### A. Personal Statement

Dr. Baylin's qualifications are relevant to this proposal include twenty five years of leading a research effort concentrating on both basic and translational aspects of epigenetic gene regulation including abnormal gene promoter DNA methylation and associated gene silencing in cancer. This research includes efforts to elucidate the basic mechanisms involved in the initiation and maintenance of DNA and other epigenetic modifications associated with tumor initiation, progression, and recurrence. His research including the analysis of TCGA data has improved our understanding of the biology of epigenetically regulated genes and has contributed to large scale collaborative translational studies aimed at using DNA methylation as cancer biomarkers. His recent research has increasingly focused on the roles of histone modification, DNA methylation and subsequent gene expression changes in cancer stem cell fate determination and on developing cancer therapies based on reversing epigenetic gene silencing. He is the faculty leader of the microarray facility at the Johns Hopkins Sidney Kimmel Comprehensive Cancer Center and responsible in that capacity for running genome screening technologies, and attendant informatics analyses, to discover epigenetic abnormalities in cancer. Dr. Baylin serves as the Deputy Director of the SKCCC as well as Co-Program Leader of the Cancer Biology Program.

### B. Positions and Honors

#### Positions and Employment

1969-71	Research Investigator, U.S. Public Health Service, National Heart & Lung Institute, Bethesda, MD
1974-	Active Staff, The Johns Hopkins Hospital, Baltimore, MD
1974-79	Assistant Professor of Oncology and Medicine, The Johns Hopkins University School of Medicine, Baltimore, MD
1979-86	Associate Professor of Oncology, The Johns Hopkins University School of Medicine, Baltimore, MD
1979-90	Associate Professor of Medicine, The Johns Hopkins University School of Medicine, Baltimore, MD
1986-	Professor of Oncology, The Johns Hopkins University School of Medicine, Baltimore, MD
1990-	Professor of Medicine, The Johns Hopkins University School of Medicine, Baltimore, MD
1991-	Director, Cancer Biology Program, Oncology Center, The Johns Hopkins University School of Medicine, Baltimore, MD
1992-	Associate Director for Research, The Johns Hopkins Comprehensive Cancer Center, Baltimore, MD
1996-	The Virginia and D.K. Ludwig Professorship in Cancer Research, The Johns Hopkins University School of Medicine, Baltimore, MD
2007-	Deputy Director, The Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins, Baltimore, MD

#### Honors

1996	Appointed to The Virginia and D.K. Ludwig Professorship in Cancer Research
------	--



2003	The Fourth Annual Jerome I. Kleinerman Lectureship in Pulmon Pathobiol, Case Western Res, SOM., Jack Shultz Memorial Lecture in Genetics, Fox Chase Cancer Center
2004-2009	Board of Directors, American Association for Cancer Research, Philadelphia, PA Recipient of Kirk A. Landon-American Association for Cancer Research Prize for Basic Cancer Research
2010	14th NCI Alfred G. Knudson Award in Cancer Genetics
2011	American Cancer Societys Medal of Honor Award

**Additional recent publications of importance to the field (in chronological order)**

1. Jones PA, Baylin SB. The epigenomics of cancer. *Cell*. 2007 Feb 23;128(4):683-92. PMID: Not supported with NIH funding.
2. Yi JM, Tsai HC, Glockner SC, Lin S, Ohm JE, Easwaran H, James CD, Costello JF, Riggins G, Eberhart CG, Laterra J, Vescovi AL, Ahuja N, Herman JG, Schuebel KE, Baylin SB. Abnormal DNA methylation of CD133 in colorectal and glioblastoma tumors *Cancer Res*. 2008;(19):8094-103. PMID: 2744404.
3. Easwaran HP, Van Neste L, Cope L, Sen S, Mohammad HP, Pageau GJ, Lawrence JB, Herman JG, Schuebel KE, Baylin SB. Aberrant silencing of cancer-related genes by CpG hypermethylation occurs independently of their spatial organization in the nucleus *Cancer Res*. 2010;(20):8015-24 NIHMSID # 263537 PMID Journal. PMID: 3031132.
4. Tiwari VK, Baylin SB. Mapping networks of protein-mediated physical interactions between chromatin elements. *Current protocols in molecular biology / edited by Frederick M. Ausubel ... [et al.]*. 2010 Jan;Chapter 21:Unit 21.16.1-13. PMID: 2857687.
5. Noushmehr H, Weisenberger DJ, Diefes K, Phillips HS, Pujara K, Berman BP, Pan F, Pelloski CE, Sulman EP, Bhat KP, Verhaak RG, Hoadley KA, Hayes DN, Perou CM, Schmidt HK, Ding L, Wilson RK, Van Den Berg D, Shen H, Bengtsson H, Neuvial P, Cope LM, Buckley J, Herman JG, Baylin SB, Laird PW, Aldape K. Identification of a CpG island methylator phenotype that defines a distinct subgroup of glioma. *Cancer cell*. 2010 May 18;17(5):510-22. PMID: 2872684.
6. Ohm JE, Mali P, Van Neste L, Berman DM, Liang L, Pandiyan K, Briggs KJ, Zhang W, Argani P, Simons B, Yu W, Matsui W, Van Criekinge W, Rassool FV, Zambidis E, Schuebel KE, Cope L, Yen J, Mohammad HP, Cheng L, Baylin SB. Cancer-related epigenome changes associated with reprogramming to induced pluripotent stem cells. *Cancer research*. 2010 Oct 1;70(19):7662-73. PMID: 2980296.
7. O'Hagan HM, Wang W, Sen S, Destefano Shields C, Lee SS, Zhang YW, Clements EG, Cai Y, Van Neste L, Easwaran H, Casero RA, Sears CL, Baylin SB. Oxidative damage targets complexes containing DNA methyltransferases, SIRT1, and polycomb members to promoter CpG Islands *Cancer Cell*. 2011;(5):606-19. PMID: 3220885.
8. Baylin SB, Jones PA. A decade of exploring the cancer epigenome - biological and translational implications *Nat Rev Cancer*. 2011;(10):726-34. PMID: 3307543.
9. Juergens RA, Wrangle J, Vendetti FP, Murphy SC, Zhao M, Coleman B, Sebree R, Rodgers K, Hooker CM, Franco N, Lee B, Tsai S, Delgado IE, Rudek MA, Belinsky SA, Herman JG, Baylin SB, Brock MV, Rudin CM. Combination epigenetic therapy has efficacy in patients with refractory advanced non-small cell lung cancer. *Cancer discovery*. 2011 Dec;1(7):598-607. PMID: 3353724.
10. Tsai HC, Li H, Van Neste L, Cai Y, Robert C, Rassool FV, Shin JJ, Harbom KM, Beaty R, Pappou E, Harris J, Yen RW, Ahuja N, Brock MV, Stearns V, Feller-Kopman D, Yarmus LB, Lin YC, Welm AL, Issa JP, Minn I, Matsui W, Jang YY, Sharkis SJ, Baylin SB, Zahnow CA. Transient low doses of DNA-demethylating agents exert durable antitumor effects on hematological and epithelial tumor cells. *Cancer cell*. 2012;21(3):430-46. PMID: 3312044.
11. Pandiyan K, You JS, Yang X, Dai C, Zhou XJ, Baylin SB, Jones PA, Liang G. Functional DNA demethylation is accompanied by chromatin accessibility. *Nucleic acids research*. 2013 Apr;41(7):3973-85. PMID: 3627572.
12. Easwaran H, Baylin SB. Epigenetic abnormalities in cancer find a "home on the range". *Cancer Cell*. 2013 Jan 14;23(1):1-3. PMID: 3586528.
13. Azad N, Zahnow CA, Rudin CM, Baylin SB. The future of epigenetic therapy in solid tumours--lessons from the past. *Nature reviews. Clinical oncology*. 2013 May;10(5):256-66. PMID: 3730253.
14. Cai Y, Geutjes EJ, de Lint K, Roepman P, Bruurs L, Yu LR, Wang W, van Blijswijk J, Mohammad H, de Rink I, Bernards R, Baylin SB. The NuRD complex cooperates with DNMTs to maintain silencing of key colorectal tumor suppressor genes. *Oncogene*. 2013 May 27 [Epub ahead of print]. PMID: 3883927.
15. Wrangle J, Wang W, Koch A, Easwaran H, Mohammad HP, Vendetti F, Vancriekinge W, Demeyer T, Du Z, Parsana P, Rodgers K, Yen RW, Zahnow CA, Taube JM, Brahmer JR, Tykodi SS, Easton K, Carvajal RD,

**BIOGRAPHICAL SKETCH**

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2. Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Dalla-Favera, Riccardo MD		POSITION TITLE Professor of Pathology and Genetics & Development	
eRA COMMONS USER NAME (credential, e.g., agency login) DALLAFAVERAR			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	MM/YY	FIELD OF STUDY
University of Milan	MD	1976	Medicine

**A. Personal Statement**

My research activity during the past 3 decade has consistently focused on the understanding of the molecular mechanisms responsible for lymphoma development, and in particular on the identification and characterization of genetic lesions that contribute to the transformation and progression of mature B cell lymphomas. In this regard, my laboratory has developed and characterized several mouse models for mature B cell malignancies, which closely resemble the relevant human diseases. In recent years, we have developed extensive experience using next generation sequencing and advance system biology tools to characterize B cell malignancies.

**B. Positions and Honors**

**Positions and Employment**

- 1983-1987 Assistant Professor, Department of Pathology, New York University School of Medicine
- 1987-1989 Associate Professor, Department of Pathology, New York University School of Medicine
- 1989-1991 Associate Professor, Department of Pathology, Columbia University
- 1989-1994 Member, Pathology B Study Section, Division of Research Grants, NIH
- 1991- Professor, Department of Pathology, Columbia Univ., College of Physicians & Surgeons
- 1992-1998 Director, Division of Experimental Oncology, Department of Pathology, Columbia University
- 1992- Professor, Department of Genetics & Development, Columbia University
- 1992- Joanne and Percy Uris Professor of Clinical Medicine, Columbia University
- 1992-1997 Deputy Director, Cancer Center Columbia University, College of Physicians & Surgeons
- 1999- Director, Institute for Cancer Genetics, Columbia University
- 2000-2002 Co-Chair, Leukemia/Lymphoma/Myeloma Program Review Group, National Cancer Institute
- 2005-2011 Director, Herbert Irving Comprehensive Cancer Center
- 2011- Professor, Department of Microbiology and Immunology, Columbia University

**Professional Societies**

- 1982 American Association for the Advancement of Science
- 1983 American Association for Microbiology
- 1984 American Association of Pathologist
- 1988 American Society of Hematology
- 1991 American Association for Cancer Research

**Awards and Honors**

- 1981 Leukemia Society of America Special Fellow
- 1984 Leukemia Society of America Scholar
- 1986 "Milano Medicina" Senior Award for Biomedical Research
- 1986 President's Research Development Award, Leukemia Society of America
- 1987 Irma T. Hirschl Research Career Award

Program Director/Principal Investigator (Last, First, Middle):

1987 Stohman Award, Leukemia Society of America  
1989 N.I.H., MERIT Award  
1994 Annual Guest Lecture Award, Leukemia Research Fund, U.K.  
1995 Dean's Distinguished Lecture, Columbia University  
1998 Fellow, American Association of Physicians  
2002 N.I.H., MERIT Award  
2005 Outstanding Achievement Award, American-Italian Cancer Foundation  
2006 William Dameshek Prize, American Society of Hematology  
2010 Member, Institute of Medicine, National Academy of Sciences  
2012 Alfred Knudson Award, National Cancer Institute

### **Other Professional Activities**

#### ***Consultative:***

1989-1993 Member, Pathology B Study Section, National Cancer Institute.  
1992-1993 Member, AIDS-associated Malignancy Task Force, National Cancer Institute  
1994- Member, Scientific Advisory Board, Yale University Cancer Center  
1995-2002 Chairman, Scientific Advisory Board, Yale University Cancer Center  
1995-2000 Member, Board of Scientific Counselors, National Institute of Environmental Health Sciences  
1997-2001 Member, Advisory Board, Cardinal Bernardin Cancer Center, Loyola University  
1998-2001 Member, Board of Guarantors, Italian Academy for Advanced Studies in America, Columbia University  
2000 Co-Chairman, National Cancer Institute Progress Review Group on Leukemia/Lymphoma/Myeloma, N.I.H.  
2001 Co-organizer, Keystone Symposium on "B Cells in Biology and Disease", Keystone, CO  
2005- Member, Scientific Advisory Board, Cancer Center, A. Einstein College of Medicine  
2005- Member, Scientific Committee on Lymphocyte Biology, American Society of Hematology  
2005- Member, World Committee, International Association for Comparative Research in Leukemia and Related Diseases  
2007 Co-organizer, CNIO Cancer Conference on: "Molecular Mechanisms in Lymphoid Neoplasm", Madrid, Spain.

#### ***Editorial:***

1987-1991 Oncogene Research (Editorial Board)  
1987-1991 Blood (Editorial Board)  
1988-1991 Leukemia (Advisory Board)  
1988-1995 Hematologic Pathology (Editorial Board)  
1989-1995 Genes, Chromosomes and Cancer (Editorial Board)  
1990-1995 Cancer Research (Associate Editor)  
1991-1996 American Journal of Pathology (Associate Editor)  
1994-2006 The Cancer Journal (Editorial Board)  
1997-2001 Blood (Editorial Board)  
1997-2002 Laboratory Investigation (Editorial Board)  
1997-2004 American Journal of Pathology (Editorial Board)  
2001-2007 Journal of Clinical Investigation (Associate Editor)  
2007- Journal of Clinical Investigation (Consulting Editor)  
2012- Cancer Cell (Editorial Board)

### **C. Selected Peer-reviewed Publications (Publications selected from 246 peer-reviewed publications)**

1) Dalla-Favera, R., Martinotti, S., Gallo, R.C., Erikson, J., and Croce, C.M.: Translocation and rearrangements of the c-myc oncogene locus in human undifferentiated B-cell lymphomas. **Science** 219:963-967, 1983. N/A

2) Gelmann, E.P., Psallidopoulos, M.C., Papas, T.S., and Dalla-Favera, R.: Identification of reciprocal translocation points within the c-myc and immunoglobulin m loci in a Burkitt lymphoma. **Nature** 306:799-803, 1983. N/A

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## BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.  
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

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NAME DiPersio, John F.	POSITION TITLE Professor of Medicine, Pathology & Pediatrics		
eRA COMMONS USER NAME jdipersi			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	YEAR(s)	FIELD OF STUDY
Williams College, Williamstown, MA	B.A.	1973	Biology
University of Rochester, Rochester, NY	M.D.	1980	Medicine
University of Rochester, Rochester, NY	Ph.D.	1980	Microbiology

---

### A. Personal Statement

N/A

### B. Positions and Employment

#### Positions and Employments

1980-1984	Intern, Resident, and Chief Resident Internal Medicine, Parkland Mem. Hospital, University of Texas, Southwestern Medical Center at Dallas, TX
1984-1987	Fellow, Division of Hematology-Oncology, UCLA School of Medicine
1987-1990	Assistant Professor of Medicine, Division of Hematology-Oncology, UCLA School of Medicine
1990-1994	Director, Bone Marrow Transplant Program, Strong Memorial Hospital, Rochester, NY
1990-1994	Assistant Professor of Medicine, Hematol Unit, Univ of Rochester Sch of Med, Rochester, NY
1994-1997	Associate Professor of Medicine, Pathology & Immunol, Washington Univ School of Medicine
1994-2000	Chief, Div of Bone Marrow Transplant Stem Cell Biology, Washington Univ School of Medicine
1997-2000	Acting Chief, Division of Medical and Mol. Oncology, Washington Univ School of Medicine
1997-present	Professor of Medicine, Pediatrics, and Pathology, Washington University School of Medicine
2000-present	Deputy Director, Siteman Cancer Center, Washington University School of Medicine
2000-2006	Director, Section of BMT and Leukemia, Washington University School of Medicine
2000-present	Chief, Division of Oncology, Washington University School of Medicine
2006-2011	Scientific Director, Good Manufacturing Procedure (GMP) Facility; Siteman Cancer Center

#### Selected Honors and Professional Memberships

1996	Elected, American Society of Clinical Investigation (ASCI)
1997	Recipient, Lewis T. and Rosalind B. Apple Chair in Oncology
2000-06	Leukemia and Lymphoma Society of America, Career Development Award Study Section Member
2000	Chairman, NHLBI Consensus Conference on Allo Transplantation for Non-Malignant Diseases
2001	ISHAGE Meeting. First prize, Scientific Merit: "Control of GvHD using genetically modified T cells."
2002	Member, Executive Committee IBMTR/ABMTR
2003-06	Award Member, ASH Committee on Educational Affairs, Washington D.C.
2003-06	Member, Board of Directors, American Society of Biology and Marrow Transplant.
2004-09	NCI (NIH) Permanent member CONC Study Section Member
2005	Chairman, Study Section RFA HL-04-017 (NHLBI) Spec. Ctr. for Cell Based Therapy.
2006	NIH (ZRG)/CSR – Gene Therapy and Inborn Errors – Special Emphasis Review Panel
2006	Member, ASH Committee on Gene and Cell Therapy
2007-12	Co-Chair, CIBMTR Acute Leukemia Working Committee
2008	"Great Teacher" Lecture NIH
2008	NCI P01 Special Emphasis Panel ZCA1-RPRB-J, October 2008, Bethesda MD
2008-	ASH Scientific Committees on Cell and Gene Therapy and Hematopoiesis

- 2008-11 Member, Scientific and Medical Research Funding; California Instit Regen. Med (CIRM)
- 2009 Member, Review Panel; Center Grants, National Medical Research Council, Singapore
- 2009 Member, ASBMT Committee on Research Priorities
- 2010 Recipient, Virginia E. and Samuel J. Golman Endowed Professorship in Medicine
- 2010 ASH/CRTI Faculty/Mentor
- 2010 Washington University Divisions of Hematology and Oncology: "Teacher of the Year"
- 2010 Member, External Advisory Board, Cancer Therapy and Research Center, UT San Antonio
- 2010 Chairman, NIH NIAID ZAI1 MFH-01 P01 Special Emphasis Panel
- 2011 NIH (BST-M)/CSR- Special Emphasis Panel
- 2011 Study Section, Doris Duke Center Grants for Sickle Cell Disease
- 2011 Chairman, NIH/NIDDK P01 Special Emphasis Panel, Methylation and Hematopoiesis
- 2012- Vice Chair (2012-13) and Chair (2013-14) ASH Scientific Committee on Hematopoiesis
- 2013 Reviewer of NCI Intramural Program: Experimental Transplantation and Immunology Branch
- 2013 NIH Study Section for Loan Repayment Program
- 2013 Daniel P. Schuster Distinguished Translational Investigator Award, Washington University
- 2013 Member, Association of American Physicians (AAP)
- 2013 Member, NCI Provocative Questions B Study Section
- 2103 Member AIDS Malignancy Consortium (AMC) Study Section Review Intramural Program
- 2013-18 Member Board of Scientific Councilors; National Cancer Institute (NCI)
- 2014 Recipient 19<sup>th</sup> Annual AACR Joseph H. Burchenal Memorial Award for Outstanding Achievement in Clinical Cancer Research

**C. Selected peer-reviewed publications (selected from 262)**

1. Rettig MP, Ritchey JK, Meyerrose TE, Haug JS, DiPersio JF: Transduction and selection of human T cells with novel CD34/thymidine kinase chimeric suicide genes for the treatment of graft-versus-host disease. *Mol Ther* 8:29-41, 2003
2. Rettig MP, Ritchey JK, Prior JL, Haug JS, Piwnica-Worms D, DiPersio JF: Kinetics of in vivo elimination of suicide gene-expressing T cells affects engraftment, graft-versus-host disease, and graft-versus-leukemia after allogeneic bone marrow transplantation. *J.Immunol*, 173:3620-3630, 2004
3. Nervi B, Rettig MP, Ritchey JK, Wang HL, Bauer G, Walker J, Bonyhadi ML, Berenson RJ, Prior JL, Piwnica-Worms D, Nolta JA, DiPersio JF. Factors affecting human T cell engraftment, trafficking and associated xenogeneic graft-vs. host disease in NOD/SCID beta2m (null) mice. *Exp Hematol* 35:1823-1838, 2007
4. Ley TJ, Mardis ER, Ding L, Fulton B, McLellan MD, Chen K, Dooling D, Dunford-Shore BH, McGrath S, Hickenbotham M, Cook L, Abbott R, Larson DE, Koboldt DC, Pohl C, Smith S, Hawkins A, Abbott S, Locke D, Hillier LW, Miner T, Fulton L, Magrini V, Wylie T, Glasscock J, Conyers J, Sander N, Shi X, Osborne JR, Minx P, Gordon D, Chinwalla A, Zhao Y, Ries RE, Payton JE, Westervelt P, Tomasson MH, Watson M, Baty J, Ivanovich J, Heath S, Shannon WD, Nagarajan R, Walter MJ, Link DC, Graubert TA, DiPersio JF, Wilson RK. DNA sequencing of a cytogenetically normal acute myeloid leukemia genome. *Nature*. 2008 Nov 6;456(7218):66-72.. PMID: PMC2303574
5. DiPersio, J. F., Stadtmauer, E. A., Nademanee, A., Micallef, I. N., Stiff, P. J., Kaufman, J. L., Maziarz, R.T., Hosing, C., Fruehauf, S., Horwitz, M., Cooper, D., Bridger, G., Calandra, G. Plerixafor and G-CSF versus placebo and G-CSF to mobilize hematopoietic stem cells for autologous stem cell transplantation in patients with multiple myeloma. *Blood*, 2009 Jun 4;113(23) 5720-6 Epub 2009 Apr 10. PMID: PMC Journal
6. Mardis ER, Ding L, Dooling DJ, Larson DE, McLellan MD, Chen K, Koboldt DC, Fulton RS, Delehaunty KD, McGrath SD, Fulton LA, Locke DP, Magrini VJ, Abbott RM, Vickery TL, Reed JS, Robinson JS, Wylie T, Smith SM, Carmichael L, Eldred JM, Harris CC, Walker J, Peck JB, Du F, Dukes AF, Sanderson GE, Brummett AM, Clark E, McMichael JF, Meyer RJ, Schindler JK, Pohl CS, Wallis JW, Shi X, Lin L, Schmidt H, Tang Y, Haipok C, Wiechert ME, Ivy JV, Kalicki J, Elliott G, Ries RE, Payton JE, Westervelt P, Tomasson MH, Watson MA, Baty J, Heath S, Shannon WD, Nagarajan R, Link DC, Walter MJ, Graubert TA, DiPersio JF, Wilson RK, Ley TJ. Recurring mutations found by sequencing an acute myeloid leukemia genome. *N Engl J Med*. 2009 Aug 5; 361:1058-66, 2009. PMID: PMC3201812
7. Choi, J., Ritchey, J., Prior, J. L., Holt, M., Shannon, W. D., Deych, E., Piwnica-Worms, D. R., and DiPersio, J. F. In vivo administration of hypomethylating agents mitigate graft-versus-host disease (GvHD) without sacrificing graft-versus-leukemia (GvL). *Blood*; 2010. Jul 8;116(1):129-39 PMID: PMC2904576
8. Cashen, A. F., Schiller, G. J., O'Donnell, M. R., and DiPersio, J. F. Multicenter, phase II study of

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## BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.  
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

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NAME Stephan Grupp MD PhD	POSITION TITLE Professor of Pediatrics CCCR Director of Translational Research
eRA COMMONS USER NAME sgrupp	

EDUCATION/TRAINING (*Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.*)

INSTITUTION AND LOCATION	DEGREE (if applicable)	YEAR(s)	FIELD OF STUDY
Univ. of Cincinnati, Cincinnati	B.S.	1981	Biology
Univ. of Cincinnati, Cincinnati	Ph.D.	1985	Immunology
Univ. of Cincinnati, Cincinnati	M.D.	1987	Medicine

### **A. Personal Statement**

I have extensive experience in the development and preclinical testing of signal transduction inhibitors in leukemia, in pediatric immunotherapy trials using signal transduction inhibitors and cell therapies, and in the manufacture and use of cellular therapeutics in preclinical, GMP, and clinical trial settings. I am the Chair of Stem Cell Transplantation for the Children's Oncology Group, the Medical Director of the CHOP GMP Stem Cell Lab, on the Boards of the Penn Cell and Vaccine Production Facility and Human Immunology Core, and the Director of Translational Research for the Center for Childhood Cancer Research at CHOP. In addition, I serve on the Pediatric Program Committee for ASBMT and the Steering Committee of the BMT Clinical Trials Network.

### **B. Positions and Employment**

1978-1981 Research Assistant Marine Biological Laboratory, Woods Hole, MA  
1981 Research Assistant, NINCDs, National Institutes of Health, Bethesda, MD  
1981-1987 Student, Medical Scientist Training Program, University of Cincinnati College of Medicine  
1987-1989 Resident in Pediatrics, Children's Hospital, Boston, MA  
1989-1992 Fellow, Pediatric Heme/Onc, Dana Farber Cancer Institute and Children's Hospital, Boston, MA  
1991-1995 Research Fellow in Immunology, Brigham and Women's Hospital, Boston, MA  
1992-1995 Instructor in Pediatrics, Harvard Medical School, Boston, MA  
1992-1995 Assistant in Medicine, Children's Hospital and Dana Farber Cancer Institute, Boston, MA  
1993-1995 Assistant in Medicine, Brigham and Women's Hospital, Boston, MA  
1996-2006 Assistant Professor of Pediatrics, University of Pennsylvania  
1997- Member, Graduate Program in Immunology, University of Pennsylvania  
1999-2010 Director, Stem Cell Biology, Division of Oncology, Children's Hospital of Philadelphia  
2000- Medical Director, Stem Cell Laboratory  
2006-2011 Associate Professor of Pediatrics, University of Pennsylvania  
2007- Chair, Children's Oncology Group Stem Cell Transplant Committee  
2008- Director of Translational Research, Center for Childhood Cancer Research, CHOP  
2008- Fellowship Director, Pediatric Hematology-Oncology, CHOP  
2011- Professor of Pediatrics, University of Pennsylvania

### **Awards/Honors**

1981 *Magna cum Laude* in Biology, Univ. of Cincinnati  
1987 Bogen Award for Outstanding Medical Student Research, Univ. Cincinnati College of Medicine  
1992-1995 Special Fellowship, Leukemia Society of America  
1993-1996 Potter Fellow  
1996 NIH FIRST Award  
1997 Best Presentation Award, 5<sup>th</sup> International Mtg on Blood Cell Transplantation, Omaha, Nebraska  
1999 Sanford Young Investigator  
2002 Research Recognition Award, Leukemia and Lymphoma Society  
2007 Lifetime Achievement Award, Eagles Fly for Leukemia

**BIOGRAPHICAL SKETCH**

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2. Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Robertson Parkman		POSITION TITLE	
eRA COMMONS USER NAME (credential, e.g., agency login) RPARKMAN		Professor of Pediatrics, Molecular Microbiology and Immunology	
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)			
INSTITUTION AND LOCATION	DEGREE (if applicable)	MM/YY	FIELD OF STUDY
Amherst College, Amherst, MA	AB	1960	
Yale Univ. School of Med., New Haven, CT	MD	1965	Medicine
Yale-New Haven Hospital, New Haven, CT		1965-1966	Pediatric-Internship
Yale-New Haven Hospital, New Haven, CT		1966-1967	Pediatric-Residency
National Cancer Institute NIH, Bethesda, MD		1967-1969	Research Assoc.

**Personal Statement**

I have been actively involved in clinical hematopoietic stem cell transplantation (HSCT) for more than 40 years with a special interest in the treatment of immunological and genetic diseases. I helped establish the HSCT program at the Children’s Hospital, Boston and the Peter Brent Brigham Hospital in the late 1960’s and established the HSCT program at the Children’s Hospital Los Angeles when I moved there in 1983. Much of my laboratory and clinical work has been centered on the immunological aspects of HSCT, including the pathogenesis of graft versus host disease (GVHD) and immune reconstitution after HSCT. In addition, I directed the Arthritis Clinic at the Children’s Hospital, Boston for 5 years and have had an ongoing interest in naturally occurring autoreactive T lymphocytes and their regulation in both autoimmune diseases and chronic GVHD and have published on the subject over the last 36 years.

I was the Principal Investigator on a SCOR in HSC Biology grant for 14 years and obtained and directed the GCRC at Children’s Hospital Los Angeles from 1994 to 2002. I ran the Immunology Core Laboratory for the COBLT (Cord Blood Transplantation) Study from 1998-2006 and the Immunology Core Laboratory for a multi-center PO-1 grant to improve immune reconstitution after HSCT from 1999-2009. Thus, I have significant expertise in directing large multi-disciplinary grants and the central immunological evaluation of multi-center clinical research trials.

I was a member of the Board of External Advisors (BEA) of NHLBI (1999-2002), a member of the Human Gene Therapy Subcommittee and the full Recombinant DNA Advisory Committee (1985-1995), and continue to be the Chairperson of the NHLBI DSMB for Gene and Cell Therapies.

**A. Positions and Honors.**

Positions and Employment

- 1963-1964 USPHS Fellow, Wright-Fleming Institute, St. Mary's Hospital, London England.
- 1969-1971 Teaching Fellow in Pediatrics, Harvard Medical School, Boston, MA.
- 1970-1972 Fellow in Med. (Immunology), Childrens Hospital Medical Center, Boston, MA.
- 1971-1974 Instructor in Pediatrics, Harvard Medical School, Boston, MA.
- 1972-1976 Asst. in Med. (Immunology), Childrens Hospital Medical Center, Boston, MA.
- 1974-1978 Asst. Professor of Pediatrics, Harvard Medical School, Boston, MA.
- 1974-1982 Associate in Medicine, Peter Bent Brigham Hospital, Boston, MA.
- 1975-1979 Senior Physician, Sidney Farber Cancer Institute, Boston, MA.
- 1978-1982 Associate Professor of Pediatrics, Harvard Medical School, Boston, MA.
- 1979-1982 Senior Associate in Medicine, Childrens Hospital Medical Center, Boston, MA.
- 1979-1982 Senior Associate in Immunology, Childrens Hospital Medical Center, Boston, MA.

- 1983- 2002 Head, Division of Research Immunology/Bone Marrow Transplantation, Childrens Hospital Los Angeles, Los Angeles, CA; Professor of Pediatrics & Microbiology, University of Southern California, Keck School of Medicine.
- 1983-Pres. Professor of Pediatrics & Microbiology, University of Southern California, Keck School of Medicine; Division of Research Immunology/Bone Marrow Transplantation, Childrens Hospital Los Angeles, Los Angeles, CA.
- 2007 Lifetime Achievement Award from the American Society for Blood and Marrow Transplantation
- 2010 Lifetime Achievement Award from the Pediatric Blood and Marrow Transplant Consortium

#### Other Experience and Professional Memberships

- 1987-1991 American Cancer Society, Immunological Study Section; 1987-1991; Chairman, 1991
- 1987-1991 Gene Therapy Subcommittee of Recombinant DNA Advisory Committee
- 1991-1996 Recombinant DNA Advisory Committee
- 1995-1998 National Council American Cancer Society
- 1996-2002 AD HOC Recombinant DNA Advisory Review Committee
- 1999-2002 NHLBI, Board of Extramural Advisors
- 2001-Pres. NHLBI, Chairman, DSMB for Gene and CellularTherapy

#### **B. Selected peer-reviewed publications (in chronological order) from a total of 149.**

1. Reinherz E, **Parkman R**, Rapoport J, Rosen F, Schlossman S. Aberrations of suppressor T cells in human graft-versus-host disease. *N Engl J Med* 300:1061-1068, 1979. PMID:34791
2. Rapoport J, Mihm M, Reinherz E, Lopansri S, **Parkman R**. Acute graft-versus-host disease in recipients of bone marrow transplants from identical twin donors. *Lancet* 2:717-720, 1979. PMID:90805
3. Osband M, Lipton J, Lavin P, Levey R, Vawter G, Greenberger J, McCaffrey R, **Parkman R**. Histiocytosis-X: Demonstration of abnormal immunity, T-cell histamine H2 receptor deficiency and successful treatment with thymic extract. *N Engl J Med* 304:146-153, 1981. PMID:6449667
4. **Parkman R**, Clonal analysis of murine graft versus host disease. I. Phenotypic and functional analysis of T lymphocyte clones. *J Immunol* 136(10):3543-3548, 1986. PMID:2871104
5. DeClerck Y, Draper V, **Parkman R**. Clonal analysis of murine graft versus host disease. II. Lymphokines that stimulate fibroblast proliferation and collagen synthesis in graft versus host disease. *J Immunol* 136(10):3549-3552, 1986. PMID:3486213
6. **Parkman R**. Graft versus host disease: an alternative hypothesis. *Immunol. Today* 10:362-364, 1989. PMID:2692593
7. **Parkman R**, Is chronic graft versus host disease an autoimmune disease? *Curr Opin Immunol* 1993;5:800-803. PMID:8240743
8. Weinberg K, Annett G, Kashyap A, Lenarsky C, Forman SJ, **Parkman R**. The Effect of Thymic Function on Immunocompetence Following bone Marrow Transplantation. *Biol Blood Marr Transplant* 1:18-23, 1995. PMID:9118285
9. **Parkman R**, Cohen G, Carter SL, Weinberg KI, Masinsin B, Guinan E, Kurtzberg J, Wagner JE, Kernan NA. Successful immune reconstitution decreases leukemic relapse and improves survival in recipients of unrelated cord blood transplantation. *Biol Blood Marrow Transplant* 12(9):919-927, 2006. PMID:16920557
10. Shah AJ, Kapoor N, Crooks GM, Weinberg KI, Azim HA, Killen R, Kuo L, Rushing T, Kohn DB, **Parkman R**. The effects of Campath 1H upon graft-versus-host disease, infection, relapse, and immune reconstitution in recipients of pediatric unrelated transplants. *Biol Blood Marrow Transplant* 13:584-593, 2007. PMID:17448918
11. Reiff A, Krogstad P, Moore S, Shaham B, **Parkman R**, Kitchen C, Weinberg K. Study of thymic size and function in children and adolescents with treatment refractory systemic sclerosis eligible for immunoablative therapy. *Clin Immunol* 133:295-302, 2009. PMID:19793681
12. Reiff A, Shaham B, Weinberg KI, Crooks GM, **Parkman R**. Anti-CD52 antibody mediated immune ablation with autologous immune recovery for the treatment of refractory juvenile polymyositis. *J Clin Immunol* 31(4):615-22, 2011. PMID:21541793
13. Candotti F, Shaw KL, Muul L, Carbonaro D, Sokolic R, Choi C, Schurman SH, Garabedian E, Kesserwan C, Jagadeesh GJ, Fu PY, Gschweng E, Cooper A, Tisdale JF, Weinberg KI, Crooks GM, Kapoor N, Shah A, Abdel-Azim H, Yu XJ, Smogorzewska M, Wayne AS, Rosenblatt HM, Davis CM, Hanson C, Rishi RG,



## BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.  
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Simon N. Powell		POSITION TITLE	
eRA COMMONS USER NAME SNPOWELL		Professor and Chair	
EDUCATION/TRAINING ( <i>Begin with baccalaureate or other initial professional education, include postdoctoral training.</i> )			
INSTITUTION AND LOCATION	DEGREE (if applicable)	YEAR(s)	FIELD OF STUDY
University of Oxford, UK	B.A.	08/1976	Physiology
University of London, UK	M.B. B.S.	07/1981	Medicine (=MD equivalent)
University of London, UK	Ph.D.	06/1991	Cell/Molecular Biology

### A. Personal Statement

I have worked in radiation oncology and biology for 28 years. I am now Chair of Radiation Oncology at Memorial Sloan-Kettering Cancer Center. I have been continuously funded by the NIH since 1992, all projects being in the area of DNA repair. I am broadly knowledgeable in all aspects of the effects of radiation on cells and humans. The cellular effects of ionizing radiation are complex, including effects on the nucleus and the membrane/cytoplasm. Nuclear effects include the production of DNA strand breaks, with our laboratory focusing on the repair of double-stranded breaks in DNA. I am interested in polymorphic variants of DNA repair genes, and their potential role in individual differences in radiation sensitivity. In studying DNA double-strand break repair, we have mostly focused on those repair features that can be disrupted in cancer cells, which can present a potential therapeutic opportunity in cancer treatment. We have spent many years looking at the effects of p53 on regulating aspects of DNA repair, including the suppression of homologous recombination, which appears to work at the level of replication. In recent years we have continued to focus on the pathway of homologous recombination and the role of the breast cancer susceptibility genes, BRCA1 and BRCA2. This avenue of work led to an interest in how the replication fork manages impediments to its progression, which is fundamental to the genomic instability of certain types of breast and ovarian cancer. We are currently working on methods to improve the efficacy of radiation therapy and drugs to exploit cancer cell DNA repair deficiencies: using both high throughput drug screens and biologically-targeted therapies. Understanding the biology of blocked replication forks will lead to additional opportunities for exploiting a tumor specific defect in DNA metabolism.

### B. Positions and Honors

#### Research and Professional Experience:

1981-4	House and Senior House Officer	General (Internal) Medicine Training in London
1984-5	Junior Lecturer	Academic Unit of Radiotherapy The Royal Marsden Hospital, Surrey
1985-8	Registrar	Department of Radiotherapy and Oncology The Royal Marsden Hospital, London/Surrey
1988-91	Clinical Scientist	The Institute of Cancer Research, Sutton, Surrey
1988-91	Honorary Senior Registrar	The Royal Marsden Hospital, London and Surrey
1991-4	Fellow / Instructor	Harvard Medical School
1994-7	Assistant Professor	Harvard Medical School
	Assistant Radiation Oncologist	Department of Radiation Oncology, MGH, Boston
1998-04	Associate Professor	Harvard Medical School
2002-04	Radiation Oncologist	Department of Radiation Oncology, MGH, Boston
2004-08	Professor and Chairman	Radiation Oncology, Washington University

2008-	Attending Radiation Oncologist Department Chair Member Professor, Molecular Biology	Department of Radiation Oncology, Memorial Sloan-Kettering Cancer Center (MSKCC) Molecular Biology Program, MSKCC Weill-Cornell Graduate School of Medical Sciences
-------	--	---

#### Honors / Awards:

1976	Corpus Christi College Award	Corpus Christi College, Oxford
1976	Sidgwick Essay Prize	Corpus Christi College, Oxford
1977	Glaxo Prize	University College, London
1981	Rosenheim Award	University College, London
1988	Rohan Williams Medal	Royal College of Radiologists, UK
1990	E.S.T.R.O. Varian Award	E.S.T.R.O.
2004	Logan Lecturer	Thomas Jefferson University
2005	Bush Lecturer	Princess Margaret Hospital, Toronto
2008	Chair, Radiation Oncology Meeting	Gordon Research Conferences
2010	Merck Lecturer	Cross Cancer Institute, Edmonton

#### **C. Selected peer-reviewed publications out of 141 total**

- Xia, F., Taghian, D.G., McDonough, K.M., DeFrank, J.S., Willers, H., Iliakis, G., **POWELL, S.N.** Deficiency of the human BRCA2 leads to impaired homologous recombination but maintains normal non-homologous end-joining. *Proc Natl Acad Sci U S A*, 2001, 98, 8644-9.
- Zhang, J., Willers, H., Feng, Z., Kim, S., Weaver, D.T., Chung, J., **POWELL, S.N.** Chk2 phosphorylation of BRCA1 regulates DNA double-strand break repair. *Mol. Cell. Biol*, 2004, 24(2), 708-18.
- Romanova LY, Willers H, Blagosklonny MV, **POWELL SN.** The interaction of p53 with replication protein A mediates suppression of homologous recombination. *Oncogene*. 2004 Dec 2;23(56):9025-33.
- Zhang J, Ma Z, Treszezamsky A, **POWELL SN.** MDC1 interacts with Rad51 and facilitates homologous recombination. *Nat Struct Mol Biol*. 2005 Oct;12(10):902-9.
- Litman R, Peng M, Jin Z, Zhang F, Zhang J, **POWELL S**, Andreassen PR, Cantor SB. BACH1 is critical for homologous recombination and appears to be the Fanconi anemia gene product FANCI. *Cancer Cell*. 2005 Sep;8(3):255-65.
- Treszezamsky AD, Kachnic LA, Feng Z, Zhang J, Tokadjian C, **POWELL SN.** BRCA1- and BRCA2-deficient cells are sensitive to etoposide-induced DNA double-strand breaks via topoisomerase II. *Cancer Res*. 2007 Aug 1;67(15):7078-81.
- Willers H, Taghian AG, Luo CM, Treszezamsky A, Sgroi DC, **POWELL SN.** Utility of DNA Repair Protein Foci for the Detection of Putative BRCA1 Pathway Defects in Breast Cancer Biopsies. *Mol Cancer Res* 2009;7(8):1304-09.
- Feng Z, Scott SP, Bussen W, Sharma G, Guo G, Pandita TK, **POWELL SN.** Rad52 inactivation is synthetically lethal with BRCA2-deficiency. *Proc Natl Acad Sci U S A*. 2011 Jan 11; 108(2):686-91.
- Bott M, Brevet M, Taylor BS, Shimizu S, Ito T, Wang L, Creaney J, Lake RA, Zakowski MF, Reva B, Sander C, Delsite R, **POWELL S**, Zhou Q, Shen R, Olshen A, Rusch V, Ladanyi M. The nuclear deubiquitinase BAP1 is commonly inactivated by somatic mutations and 3p21.1 losses in malignant pleural mesothelioma. *Nat Genet*. 2011 Jun 5. [Epub ahead of print] PMID: 21642991
- Roy R, Chun J, **POWELL SN.** BRCA1 and BRCA2: different roles in a common pathway of genome protection. *Nat Rev Cancer*. 2011 Dec 23;12(1):68-78. PubMed PMID: 22193408.
- Lok BH, Carley AC, Tchang B, **POWELL SN.** RAD52 inactivation is synthetically lethal with deficiencies in BRCA1 and PALB2 in addition to BRCA2 through RAD51-mediated homologous recombination. *Oncogene*. 2012 Sep 10. [Epub ahead of print]. PMID: 22964643.
- Chun J, Buechelmaier ES, **POWELL SN.** Rad51 Paralog Complexes BCDX2 and CX3 Act at Different Stages in the BRCA1-BRCA2-Dependent Homologous Recombination Pathway. *Mol Cell Biol*. 2013; 33(2):387-95. PMID: 23149936.
- Singh M, Hunt CR, Pandita RK, Kumar R, Yang CR, Horikoshi N, Bachoo R, Sarag S, Story MD, Shay

## BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2.  
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Jerome Ritz, M.D.		POSITION TITLE Professor of Medicine Executive Director, Connell O'Reilly Cell Manipulation Core Facility	
eRA COMMONS USER NAME (credential, e.g., agency login) JEROME_RITZ			
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)			
INSTITUTION AND LOCATION	DEGREE (if applicable)	MM/YY	FIELD OF STUDY
Northwestern University, Evanston, IL	B.A.	1968	
Chicago Medical School, Chicago, IL	M.D.	1972	Medicine
University of Wisconsin Hospitals, Madison, WI		1972-75	Internal Medicine
Beth Israel Hospital, Boston, MA		1975-76	Hematology/Oncology

### A. Personal Statement

My research laboratory focuses on reconstitution and maintenance of donor immunity after allogeneic hematopoietic stem cell transplantation (HSCT). In this setting, there is compelling evidence that donor immunity plays a critical role in elimination of residual tumor cells (termed graft vs leukemia or GVL) as well as graft vs host disease (GVHD). Individual projects focus on the role of T cells, regulatory T cells, NK cells and B cells in GVL and GVHD. Mechanistic studies focus on the identification of specific antigenic targets of T, B and NK cell responses and how these immune responses are maintained and regulated in vivo. All of our studies are carried out with samples obtained from patients undergoing stem cell transplantation and lay the foundation for the development of novel methods to specifically modulate immune reconstitution and tumor immunity following HSCT. I am also the Executive Director of the Cell Manipulation Core Facility (CMCF) of the Dana-Farber/Harvard Cancer Center. The CMCF is a GMP cell manufacturing facility that provides a variety of cellular products for patients enrolled on clinical research protocols, including hematopoietic stem cells, cancer vaccines, immune cells for adoptive therapy, genetically modified cells and cells for regenerative medicine. I am also Director of the Pasquarello Tissue Bank for Hematologic Malignancies at DFCl and Associate Director for Core Facilities and member of the Executive Committee of the Dana-Farber/Harvard Cancer Center.

### B. Positions and Honors

#### Positions and Employment

1980 - 1981 Instructor in Medicine, Harvard Medical School, Boston, MA  
1981 - 1984 Assistant Professor of Medicine, Dana-Farber Cancer Institute and Harvard Medical School  
1984 - 1996 Associate Professor of Medicine, Dana-Farber Cancer Institute and Harvard Medical School  
1993 - 1997 Clinical Director, Division of Hematologic Malignancies, Dana-Farber Cancer Institute  
1996 - 2011 Director, Connell O'Reilly Cell Manipulation Core Facility, Dana-Farber Cancer Institute  
1996 - Professor of Medicine, Dana-Farber Cancer Institute and Harvard Medical School  
1997 - 1999 Director, Center for Hematologic Oncology, Dana-Farber Cancer Institute  
1999 - 2011 Senior Editor and Deputy Editor, Clinical Cancer Research  
2003 - Associate Director for Core Facilities, Dana-Farber/Harvard Cancer Center (DF/HCC)  
2004 - Co-Director, Center for Human Cell Therapy, Boston Children's Hospital and Dana-Farber Cancer Institute  
2005 - Co-Director, Cancer Vaccine Center, Dana-Farber Cancer Institute  
2005 - Executive Committee and Principal Faculty, Harvard Stem Cell Institute  
2011 - Executive Director, Connell O'Reilly Cell Manipulation Core Facility, DF/HCC

#### Honors

1983 - 1988 Scholar, Leukemia Society of America  
1988 Stohlman Scholar Award, Leukemia Society of America  
1990 American Society for Clinical Investigation

### C. Selected Peer-Reviewed Publications (from 330 original peer-reviewed publications)

1. Matsuoka KI, Kim HT, McDonough S, Warshauer B, Bascug G, Warshauer B, Koreth J, Cutler C, Ho VT, Alyea EP, Antin JH, Soiffer RJ, **Ritz J**. Altered regulatory T-cell homeostasis in patients with CD4 lymphopenia following allogeneic hematopoietic stem cell transplantation. *J Clin Invest* 2010; 120:1479-1493. PMID: 2860902
2. Kawano Y, Kim HT, Matsuoka K-I, Bascug G, McDonough S, Ho VT, Cutler C, Koreth J, Alyea EP, Antin JH, Soiffer RJ, **Ritz J**. Low telomerase activity in CD4+ regulatory T cells in patients with severe chronic GVHD after hematopoietic stem cell transplantation. *Blood* 2011; 118:5021-5030. PMID: 3208307
3. Sarantopoulos S, Stevenson KE, Kim HT, Washel WS, Bhuiya NS, Cutler CS, Alyea EP, Ho VT, Soiffer RJ, Antin JH, **Ritz J**. Recovery of B-cell homeostasis after rituximab in chronic graft-versus-host disease. *Blood*. 2011;117:2275-83. PMID: 3062333.
4. Koreth J, Matsuoka K-I, Kim HT, McDonough SM, Bindra B, Alyea EP, Armand P, Cutler C, Ho VT, Treister NS, Bienfang DC, Prasad S, Tzachanis D, Joyce RM, Avigan DE, Antin JH, **Ritz J**, Soiffer RJ. Interleukin-2 and regulatory T cells in chronic graft versus host disease. *N Engl J Med* 2011; 365:2055-66. PMID: 3727432
5. Hu D, Liu X, Zeng W, Weiner HL, **Ritz J**. A clonal model for human CD8<sup>+</sup> regulatory T cells: unrestricted contact-dependent killing of activated CD4<sup>+</sup> T cells. *Eur J Immunol* 2012; 42:69–79. PMID: 3251657
6. Jacobson CA, Turki AT, McDonough SM, Stevenson KE, Kim HT, Kao G, Herrera MI, Reynolds CG, Alyea EP, Ho VT, Koreth J, Armand P, Chen Y-B, Ballen K, Soiffer RJ, Antin JH, Cutler C, **Ritz J**. Immune reconstitution after double umbilical cord blood stem cell transplantation: comparison with unrelated peripheral blood stem cell transplantation. *Biol Blood Marrow Transplant* 2012; 18:565-574. PMID: 3288552
7. Bellucci R, Nguyen H-N, Martin A, Heinrichs S, Schinzel AC, William C. Hahn WC, **Ritz J**. Multiple tyrosine kinase pathways modulate tumor susceptibility to human natural killer cells. *J Clin Invest* 2012; 122:2369-2383. PMID: 3386806
8. Chen Y-B, McDonough S, Hasserjian R, Chen H, Coughlin E, Illiano C, Park IS, Jagasia M, Spitzer TR, Cutler CS, Soiffer RJ, **Ritz J**. Expression of CD30 in patients with acute graft-vs.-host disease. *Blood* 2012; 120:691-696. PMID: 3401221
9. Hu D, Weiner HL, **Ritz J**. Identification of cytolytic CD161<sup>+</sup>CD56<sup>+</sup> regulatory CD8 T cells in human peripheral blood. *Plos One* 2013 March 19;8(3): e59545. PMID: 3602421.
10. Burkhardt UE, Hainz U, Stevenson K, Goldstein NR, Pasek M, Naito M, Wu D, Ho VT, Alonso A, Hammond NN, Wong J, Sievers QL, Brusica A, McDonough SM, Zeng W, Perrin A, Brown JR, Canning CM, Koreth J, Cutler C, Armand P, Neuberg D, Lee JS, Antin JH, Mulligan RC, Sasada T, **Ritz J**, Soiffer RJ, Dranoff G, Alyea EP, Wu CJ. Autologous CLL cell vaccination early after transplant induces leukemia-specific T cells. *J Clin Invest*. 2013;123:3756-65. PMID: 3754265.
11. Cutler C, Kim HT, Bindra B, Sarantopoulos S, Ho VT, Chen YB, Rosenblatt J, McDonough S, Watanaboonyongcharoen P, Armand P, Koreth J, Glotzbecker B, Alyea E, Blazar BR, Soiffer RJ, **Ritz J**, Antin JH. Rituximab prophylaxis prevents corticosteroid-requiring chronic GVHD after allogeneic peripheral blood stem cell transplantation: results of a phase 2 trial. *Blood*. 2013;122:1510-7. PMID: 3750344.
12. Matsuoka K, Koreth J, Kim HT, Bascug G, McDonough S, Kawano Y, Murase K, Cutler C, Ho VT, Alyea EP, Armand P, Blazar BR, Antin JH, Soiffer RJ, **Ritz J**. Low-dose interleukin-2 therapy restores regulatory T cell homeostasis in patients with chronic graft-versus-host disease. *Sci Transl Med*. 2013;5:179ra43. PMID: 3686517.
13. Nikiforow S, Kim HT, Bindra B, McDonough S, Glotzbecker B, Armand P, Koreth J, Ho VT, Alyea EP, 3rd, Blazar BR, **Ritz J**, Soiffer RJ, Antin JH, Cutler CS. Phase I study of alemtuzumab for therapy of steroid-refractory chronic graft-versus-host disease. *Biol Blood Marrow Transplant*. 2013;19:804-11. PMID: 3642980.
14. Bachireddy P, Hainz U, Rooney M, Pozdnyakova O, Aldridge J, Zhang W, O'Connell K, Haining WN, Goldstein NR, Canning CM, Soiffer RJ, **Ritz J**, Hacohen N, Alyea EP, Kim HT, Wu CJ. Reversal of *in situ* T cell exhaustion during effective human anti-leukemia responses to donor lymphocyte infusion. *Blood* 2014; 123:1412-1241. PMID: 3938152.

## BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2. Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Alessandro Sette		POSITION TITLE Professor and Head Division of Vaccine Discovery	
eRA COMMONS USER NAME (credential, e.g., agency login) ASETTE			
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)			
INSTITUTION AND LOCATION	DEGREE (if applicable)	MM/YY	FIELD OF STUDY
Liceo Classico "T. Tasso", Rome, Italy	Maturita	1979	Humanistic Studies
University of Rome, Rome, Italy	Laurea	1984	Immunology
Laboratory of Pathology, Casaccia, Rome, Italy	Postdoc	1984-1985	
National Jewish Center for Immunology and Respiratory Medicine, Denver, CO	Postdoc	1986-1988	

### A. Personal Statement

Alessandro Sette, Dr. Biol.Sc., has devoted more than 25 years to understanding and measuring immune responses, and developing disease intervention strategies against autoimmunity, cancer and infectious diseases. Working in the laboratory of Howard Grey in Denver, he was involved in some of the original studies demonstrating peptide binding to MHC Class II molecules, and developed the first computerized allele specific prediction based on sequence analysis. In subsequent studies, while at Cytel corporation, he investigated the use of peptides to modulate autoimmunity and in the early 1990s discovered the phenomenon of TCR antagonism. TCR antagonism has been widely used as a strategy to modulate autoimmunity, infectious disease and cancer specific immune responses. His subsequent work showed that antigen analogs can also act in modulating immune responses (partial agonist) or even be associated with higher potency than cognate antigens (heteroclitic analogs). He currently directs the immune epitope database (IEDB) and specializes in identifying CD4 and CD8 activating peptide epitopes.

### B. Positions and Honors

1988-1989 Staff Scientist, Cytel Corporation, San Diego, CA  
1989-1990 Senior Staff Scientist, Cytel Corporation, San Diego, CA  
1990-1992 Associate Director of Immunochemistry, Cytel Corporation, San Diego, CA  
1992-1994 Director of Immunochemistry, Cytel Corporation, San Diego, CA  
1994-1996 Director of Immunology, Cytel Corporation, San Diego, CA  
1996-2002 Chief Scientific Officer, Epimmune Inc., San Diego, CA  
2002-Present Tenured Member, La Jolla Institute for Allergy and Immunology, San Diego, CA

### Other Experience and Professional Membership

1992-1998 Associate Editor, the Journal of Immunology  
1993- Peer Review Consultant, National Institutes of Health and National Cancer Institute  
1994-1997 Member, Arthritis Foundation Study Section, Cellular Immunology  
1996 Ad Hoc Consultant for National Science Foundation, European Science Institute, Istituto Superiore di Sanita, Wellcome Trust, ITN and other funding agencies  
1998-1999 Member, HIV Vaccines Study Session, National Institutes of Health  
1998 Editorial Board Member: Human Immunology, Current Pharmaceutical Biotechnology; Current Drugs, Tissue Antigens  
2002-2005 Vice President, American Liver Foundation, San Diego Chapter  
2002 Member, Gerson Lehman Council of Healthcare Advisors  
2002-2007 Adjunct Professor, The Scripps Research Institute, San Diego, CA  
2003-2009 Adjunct Professor, University of California, San Diego, CA

*Editorial Board Member:* for Human Immunology, Current Pharmaceutical Biotechnology; Current Drugs, Tissue Antigens, Immunogenetics, Expert Rev Vaccines, Open Immunol and PLoS One. *Memberships:* Amer Assoc Immunologists, Amer Assoc Microbiologists, Amer Soc Microbiol, Amer Chemical Soc, Protein Soc, NY Acad Sci, Amer Assoc Cancer Res

### **C. Selected Peer-Review Publications (492 publications; 96 reviews/chapters)**

- Rivoltini L, Kawakami Y, Sakaguchi K, Southwood S, Sette A, Robbins PF, Marincola FM, Salgaller ML, Yannelli JR, Appella E, et al. Induction of tumor-reactive CTL from peripheral blood and tumor-infiltrating lymphocytes of melanoma patients by in vitro stimulation with an immunodominant peptide of the human melanoma antigen MART-1. *J Immunol.* 1995;154(5):2257-65. PMID:7868898.
- Kawakami Y, Eliyahu S, Jennings C, Sakaguchi K, Kang X, Southwood S, Robbins PF, Sette A, Appella E, Rosenberg SA. Recognition of multiple epitopes in the human melanoma antigen gp100 by tumor-infiltrating T lymphocytes associated with in vivo tumor regression. *J Immunol.* 1995;154(8):3961-8. PMID:7706734.
- Bocchia M, Wentworth PA, Southwood S, Sidney J, McGraw K, Scheinberg DA, Sette A. Specific binding of leukemia oncogene fusion protein peptides to HLA class I molecules. *Blood.* 1995;85(10):2680-4. PMID:7742526.
- Ressing ME, Sette A, Brandt RM, Ruppert J, Wentworth PA, Hartman M, Oseroff C, Grey HM, Melief CJ, Kast WM. Human CTL epitopes encoded by human papillomavirus type 16 E6 and E7 identified through in vivo and in vitro immunogenicity studies of HLA-A\*0201-binding peptides. *J Immunol.* 1995;154(11):5934-43. PMID:7538538.
- Celis E, Sette A, Grey HM. Epitope selection and development of peptide based vaccines to treat cancer. *Semin Cancer Biol.* 1995;6(6):329-36. Review. PMID:8938271.
- Ressing ME, van Driel WJ, Celis E, Sette A, Brandt MP, Hartman M, Anholts JD, Schreuder GM, ter Harmsel WB, Fleuren GJ, Trimbos BJ, Kast WM, Melief CJ. Occasional memory cytotoxic T-cell responses of patients with human papillomavirus type 16-positive cervical lesions against a human leukocyte antigen-A \*0201-restricted E7-encoded epitope. *Cancer Res.* 1996;56(3):582-8. PMID:8564975.
- Bocchia M, Korontsvit T, Xu Q, Mackinnon S, Yang SY, Sette A, Scheinberg DA. Specific human cellular immunity to bcr-abl oncogene-derived peptides. *Blood.* 1996 87(9):3587-92. PMID:8611681.
- Topalian SL, Gonzales MI, Parkhurst M, Li YF, Southwood S, Sette A, Rosenberg SA, Robbins PF. Melanoma-specific CD4+ T cells recognize nonmutated HLA-DR-restricted tyrosinase epitopes. *J Exp Med.* 1996;183(5):1965-71. PMC2192565.
- Parkhurst MR, Salgaller ML, Southwood S, Robbins PF, Sette A, Rosenberg SA, Kawakami Y. Improved induction of melanoma-reactive CTL with peptides from the melanoma antigen gp100 modified at HLA-A\*0201-binding residues. *J Immunol.* 1996;157(6):2539-48. PMID:8805655.
- Alexander M, Salgaller ML, Celis E, Sette A, Barnes WA, Rosenberg SA, Steller MA. Generation of tumor-specific cytolytic T lymphocytes from peripheral blood of cervical cancer patients by in vitro stimulation with a synthetic human papillomavirus type 16 E7 epitope. *Am J Obstet Gynecol.* 1996;175(6):1586-93. PMID:8987945.
- Tsai V, Southwood S, Sidney J, Sakaguchi K, Kawakami Y, Appella E, Sette A, Celis E. Identification of subdominant CTL epitopes of the GP100 melanoma-associated tumor antigen by primary in vitro immunization with peptide-pulsed dendritic cells. *J Immunol.* 1997;158(4):1796-802. PMID:9029118.
- Salazar-Onfray F, Nakazawa T, Chhajlani V, Petersson M, Kärre K, Masucci G, Celis E, Sette A, Southwood S, Appella E, Kiessling R. Synthetic peptides derived from the melanocyte-stimulating hormone receptor MC1R can stimulate HLA-A2-restricted cytotoxic T lymphocytes that recognize naturally processed peptides on human melanoma cells. *Cancer Res.* 1997;57(19):4348-55. PMID:9331097.
- Tanaka F, Fujie T, Tahara K, Mori M, Takesako K, Sette A, Celis E, Akiyoshi T. Induction of antitumor cytotoxic T lymphocytes with a MAGE-3-encoded synthetic peptide presented by human leukocytes antigen-A24. *Cancer Res.* 1997;57(20):4465-8. PMID:9377553.
- Tsai V, Kawashima I, Keogh E, Daly K, Sette A, Celis E. In vitro immunization and expansion of antigen-specific cytotoxic T lymphocytes for adoptive immunotherapy using peptide-pulsed dendritic cells. *Crit Rev Immunol.* 1998;18(1-2):65-75. Review. PMID:9419449.
- Kawashima I, Hudson SJ, Tsai V, Southwood S, Takesako K, Appella E, Sette A, Celis E. The multi-epitope approach for immunotherapy for cancer: identification of several CTL epitopes from various tumor-associated antigens expressed on solid epithelial tumors. *Hum Immunol.* 1998;59(1):1-14. PMID:9544234.
- Steller MA, Gurski KJ, Murakami M, Daniel RW, Shah KV, Celis E, Sette A, Trimble EL, Park RC, Marincola FM. Cell-mediated immunological responses in cervical and vaginal cancer patients immunized with a lipidated epitope of human papillomavirus type 16 E7. *Clin Cancer Res.* 1998;4(9):2103-9. PMID:9748126.
- Kono K, Rongcun Y, Charo J, Ichihara F, Celis E, Sette A, Appella E, Sekikawa T, Matsumoto Y, Kiessling R. Identification of HER2/neu-derived peptide epitopes recognized by gastric cancer-specific cytotoxic T



# Cancer Prevention and Research Institute of Texas

## Oversight Committee

### Nominations Subcommittee Meeting

### Peer Review Panel Nominations Product Development

1. Charles Jaffee, Ph.D
2. Chris A. Rallis, J.D.
3. Claude Nicaise, M.D.
4. Colin Turnbull Ph.D
5. Cora N. Sternberg M.D., F.A.C.P
6. Darrick T. Fu, MBA
7. David Edward Weng, M.D., Ph.D
8. Elaine Jones, Ph.D.
9. Grant A. Williams, M.D.
10. Judith A. Fox, Ph.D.
11. Michael Foley, Ph.D.
12. Lee Greenberger, Ph.D.
13. Michael Kurman, M.D.
14. Ramona M. Lloyd, Ph.D., RAC

## BIOGRAPHICAL SKETCH

NAME	Charles Jaffe	POSITION TITLE		
eRA COMMONS USER NAME		Chief Executive Officer, Health Level Seven, Inc.		
EDUCATION/TRAINING				
INSTITUTION AND LOCATION		DEGREE	YEAR(s)	FIELD OF STUDY
Johns Hopkins University, Baltimore		BA	1967	Chemistry
Duke University, Durham		MD	1971	Medicine
Duke University, Durham		PhD	1972	Experimental Pathology
Duke University, Durham			1973	Medicine
National Institutes of Health, NIAID, Bethesda			1976	Immunology
Georgetown University, Washington			1978	Hematology/Oncology

### A. Personal statement

As CEO of Health Level Seven and a member of the steering committees of the Cancer Bioinformatics Grid, NIH/NCI, Integrating the Healthcare Enterprise (IHE), and the Clinical Research Information Exchange (CRiX), NIH/NCI, Life Sciences Institute of Technology, CCHIT, and the Clinical Data Interchange Standards Consortium (CDISC), I have extensive experience in the area of clinical research and clinical information management. In addition to developing global programs for healthcare and research data integration, I have led the business development of multinational for-profit and non-profit organizations. My clinical experience includes division chairmanship and principal clinical investigator. Annually, I serve on grant review boards for the National Science Foundation and the NIH.

### B. Positions and Honors

#### Positions and Employment

1985-2000	Department of Medicine, Scripps Health, San Diego, CA
1987-1996	Assistant Clinical Professor, Department of Medicine, UCSD
1987-2000	Attending Physician, Department of Medicine, Scripps Health System, La Jolla
1991-2000	Director, Clinical Trials, Allergy & Immunology MG
1993-1998	Vice President, Biotechnology, San Diego Clinical Research, San Diego, CA
1995-1998	Western Regional Director, National Committee Program, Johns Hopkins University
1995-2000	President, InforMed, Inc., Del Mar, CA
2000-2004	Vice President Medical Informatics, AstraZeneca Pharmaceuticals LP, Wilmington, DE
2003-2007	Biosilico, Elsevier, Editor
2004-2005	Vice President Life Sciences, SAIC, La Jolla, CA
2004-2007	Professor, Department of Engineering, Penn State University, Great Valley
2005-2007	Senior Global Strategist, Digital Health Group, Intel Corporation, Santa Clara, CA
2007-	Chief Executive Officer, Health Level Seven, Inc.
2010-	Professor of Medicine, Department of Medicine, UCSD

#### Other Experience and Professional Memberships

1992-1997	Aetna-CHAMPUS, Advisory Board
1994-1997	BioMed Institutional Review Board, Chair
1997-2002	American Medical Informatics Association, Chair, Clinical Information Systems WG
2001-2007	Clinical Data Interchange Standards Consortium (CDISC), Board of Directors and Chair, Scientific Committee
2002-2003	Health Information Management Systems Society, Principal Investigator, Longitudinal study of the impact of technology for the reduction of medical errors
2002-2004	American Medical Informatics Association, Chair, Professional Relations
2002-2006	Drug Information Association, Chair, Electronic Clinical Trials SIAC
2004-2011	Cancer Bioinformatics Grid, National Institutes of Health/National Cancer Institute, Steering Committee



2004-2011 Markle Foundation, Connecting for Health, Steering Committee  
 2004-2005 Health Information Management Systems Society, Advisory Board, HIMSS Committee on Certification for the EHR  
 2004-2006 FasterCures, Steering Committee for Clinical Research Integration  
 2004-2006 Global Trial Bank, Clinical Trial Registry, Steering Committee, 2004-06 and Chair, 2006  
 2005- Clinical Research Information Exchange (CRiX), National Institutes of Health/National Cancer Institute, Steering Committee  
 2006-2007 Swiss Institute of Biotechnology, Board of Directors  
 2007- Open Health Tooling Collaborative, Board of Directors  
 2008-2011 LSIT (Life Sciences) Global Institute, Board of Directors  
 2008- Biomedical Research Integrated Domain Group (BRIDG), Board of Directors  
 2008- Integrating the Healthcare Enterprise (IHE), International Board of Directors

### **Awards and Honors**

1966 Phi Beta Kappa, Johns Hopkins University  
 1971 Alpha Omega Alpha, Duke University Medical School  
 1967-1971 National Institutes of Health Medical Scientist  
 1971 American Academy of Allergy & Clinical Immunology Clinical Fellow  
 1978 WHO Clinical Medicine Award  
 1981 University of California Distinguished Faculty Award  
 1990 Institutional Review Board Distinguished Service Award  
 1997 NIH/National Library of Medicine, Medical Informatics Grantee  
 2003 American College of Medical Informatics, Fellow  
 2006 Penn State University, Distinguished Faculty Award  
 2002-2006 Editor, Biosilico, Elsevier LLC, London  
 2003 Fellow, American College of Medical Informatics  
 2008 Fellow, American College of Physicians  
 2008 Fellow, Royal Society of Medicine  
 2011 Federal 100 Awardee  
 2012 Robert Becker, Lifetime Achievement Award, AAAAI

### **C. Selected peer-reviewed publications**

Jaffe, C, Hammond, WE, Quinn, J, Dolin, R. Healthcare Standards and the Standards Development Process. Int Tech J. 2009 Sep; 13(3): 58-79. PMID:

Blobel B, Chronaki C, Stegwee R, Grain H, Hammond WE, Jaffe C, Kalra D, Koehn M, Macary F, Sabutsch S, Sheetham E, Schulz S, Tan M; HL7 Affiliates Council. HL7's comprehensive standards set and its international collaboration for enabling semantically interoperable eHealth and pHealth solutions. Stud Health Technol Inform. 2009;150:982-6. PMID: 19745460

Hammond WE, Jaffe C, Kush RD. Healthcare standards development. The value of nurturing collaboration. J AHIMA. 2009 Jul;80(7):44-50. PMID: 19663144

Dolin RH, Rogers B, Jaffe C. Big Data, Incrementally Structured. In press.

### **D. Research Support**

N/A

## **Chris A. Rallis**

104 North Devimy Court  
Cary, North Carolina 27511  
Home: (919) 461-0988  
Cell: (919) 624-7885  
E-mail: chrisrallisnc@gmail.com

### **SUMMARY**

Team-oriented executive with diverse experience in general management, corporate law, business development and strategic planning areas of research-based and development stage pharmaceutical companies. Particular strengths include analytical, communication, negotiation and interpersonal skills and strategic focus. Successful record of completing transactions and achieving objectives in a timely and efficient manner.

### **PROFESSIONAL EXPERIENCE**

#### **A. M. PAPPAS & ASSOCIATES, LLC, Durham, NC, Executive-In-Residence      January 2008 – Present**

Served as an executive-in-residence (EIR) with A. M. Pappas & Associates (Pappas Ventures) responsible for heading an initiative to evaluate alternative enterprise models to support seed and early stage opportunities in the Florida life science sector. Project was terminated in January 2009. Since January 2009, continue to serve in EIR capacity, attending weekly portfolio review meetings, as well as presentations by some prospective portfolio companies.

#### **CIRRUS PHARMACEUTICALS, INC., Durham, NC, Consultant      January 2011 – April 2011**

Served as a consultant with Cirrus Pharmaceuticals, Inc., a formulation/product development contract research organization, to develop an operational plan to implement the objectives set forth in Cirrus' 2011-2015 Strategic Plan.

#### **IMMUNOBIOSCIENCES, INC., Raleigh, NC.      April 2006 – June 2007**

##### **President, Chief Executive Officer and Board Member**

ImmunoBiosciences (IBI) was a vaccine technology company focusing on the development of immune complex vaccines for use in the human and veterinary vaccine markets. Activities included leading the management team in the development of a strategic business plan, corporate presentations, a website and patenting strategies and making various presentations to a number of potential collaborators and investors. In addition, led management team in achieving milestone required for second tranche of Series A Financing in October 2006. IBI ceased operations in early 2011.

#### **DUKE UNIVERSITY, Durham, NC, Consultant      Dec. 2005 – March 2006 July 2005 – Sept. 2005**

Served as a consultant to Duke University in connection with its Medical School's translational research initiative. Responsible for preparation of business plan (in conjunction with team of consultants) and for assisting Duke senior management in preparation of presentations to Board of Trustees regarding implementation recommendations.

**PAPPAS VENTURES, RTP, NC, Executive-In-Residence**

**July 2004 – March 2006**

Served as a part-time executive-in-residence for Pappas Ventures, a venture capital partnership focusing on investments exclusively in the life science sector. Activities include participating in weekly portfolio review meetings and attending presentations by some prospective portfolio companies.

**PANACOS PHARMACEUTICALS, INC., Gaithersburg, MD, Consultant**

**March 2004 – June 2004**

Served as a corporate development consultant to Panacos, a privately owned HIV drug development company, in connection with a potential merger transaction. Responsible for coordination of due diligence activities with several potential acquirers and negotiation of term sheet and merger agreement with actual acquirer. Merger agreement between Panacos and V.I. Technologies, Inc. was signed in June 2004 and the merger closed in March 2005.

**TRIANGLE PHARMACEUTICALS, INC., Durham, NC**

**Nov. 1995 – December 2002**

A specialty pharmaceutical company, incorporated in 1995, focusing on the development of drugs to treat serious viral diseases, such as HIV. The Company was acquired by Gilead Sciences in January 2003 for \$464 million. The Company's first product was approved in both the U.S. and Europe in 2003.

**President, Chief Operating Officer and Board Member**

**March 2000 – Dec. 2002**

Responsible for general management of functional areas of the Company and, in conjunction with CEO and other executive officers, interfacing with financial and investment community, non-executive directors and shareholders. Supervisory responsibility for six executive vice presidents, one director and one administrative assistant. Member of the Board of Directors of the Company.

- Interim senior officer of the Company following death of CEO in January 2002 until appointment of successor in August 2002, during which time, the Company:
  - Successfully terminated collaboration with Abbott Laboratories on favorable terms.
  - Resolved two major intellectual property disputes.
  - Accelerated the preparation of its first NDA submission (beating publicly announced target submission date by one month).
- Led senior management team's implementation of corporate restructuring in August 2001 resulting in a 31% reduction in cash usage for the year.
- Participated on senior management team that developed the Company's first strategic plan.
- Led implementation of recommendations from a June 2000 Company survey in the areas of employee communications, career development and management and diversity training.
- Successfully recruited CFO and General Counsel within 90 days after appointment.
- Made Company presentations at numerous life science/healthcare investment conferences.
- Participated in negotiations of three equity financings in 2001 (with aggregate gross proceeds of \$133 million) and a \$100 million equity line of credit facility in November 2000.

**Executive Vice President, Business Development and General Counsel**

**August 1999 – March 2000**

**Vice President, Business Development, General Counsel and Secretary**

**Nov. 1995 – July 1999**

Responsible for legal and business development activities of the Company. Areas of concentration in legal area included contract negotiation and drafting (e.g., intellectual property licenses), equity financing, securities laws compliance, and trademark, patent and customs matters. Business development activities included supervising scientific and commercial evaluations of licensing candidates and negotiation of commercial terms regarding intellectual property licenses. Secretariat responsibilities included administration of Board meetings and annual stockholders meetings. Supervisory responsibility for vice president of drug regulatory affairs (from August 1999 – March 2000), 1 attorney and 1 administrative assistant.

- Lead Company counsel and business development representative in negotiation of a \$335 million worldwide strategic alliance with Abbott Laboratories completed in 1999, which included 4 Company compounds and 2 Abbott products.
- Lead Company counsel and business development representative in negotiation of 5 license agreements and 2 option agreements for Company drug candidates, including 3 of which were consummated in less than a 1 month period in 1996.
- Lead Company counsel in 7 equity financings consummated during an approximate 3½-year period, with aggregate gross proceeds of approximately \$225 million, including the Company's initial public offering in 1996.
- Lead Company counsel in \$15+ million acquisition of Avid Corporation in 1997.
- Lead Company counsel in negotiation of subleases for the Company's 100,000 square foot headquarters with Eli Lilly and Company.
- Lead Company counsel and business development representative in negotiation of license and settlement agreements with Glaxo Wellcome, Inc., resolving a patent dispute relating to one of the Company's drug candidates known as FTC.

**BURROUGHS WELLCOME CO., Research Triangle Park, NC**

**July 1982 – August 1995**

A research-based pharmaceutical company with approximately 5,000 employees and \$1.3 billion in U.S. sales in 1994. U.S. operating subsidiary of The Wellcome Foundation Limited with over \$3.3 billion in worldwide sales in 1994.

**Vice President, Planning and Business Development**

**1994 – 1995**

**Director, Planning and Business Development**

**1993 – 1994**

Responsible for business development activities of the Company in areas of product/technology licenses, research collaborations, co-promotion agreements, acquisitions and divestitures. Responsible for strategic planning activities of the Company, including the development of the Company's strategic plan and its assessment of strategic alternatives. Coordinated both business development and strategic planning activities with those of the U.K. parent company. Supervisory responsibility for 3 to 4 licensing professionals and 2 administrative assistants.

- Managed department that consummated a \$1 billion U.S. consumer healthcare products joint venture, a \$42 million license agreement and a \$17 million intellectual property acquisition within a 90-day period in 1993-1994.
- Participated in senior management review and selection of strategic alternatives in U.S. managed healthcare environment in 1994.
- Played a major role in the negotiation of a co-promotion agreement for Company's largest selling product with over \$450 million in U.S. sales in 1994.
- Participated on team that developed group-wide strategic plan in 1993.

**Attorney, Corporate Law Section**

**1982 – 1993**

Assistant General Counsel

1991 – 1993

Head of Corporate Law Section

1989 – 1993

Senior Counsel

1988 – 1991

Associate Counsel

1986 – 1988

Assistant Counsel

1982 – 1986

Responsible for providing legal advice to Company clients in general corporate law area, with primary emphasis on contract drafting and negotiation (including the following types of contracts: licenses, manufacturing, co-promotion, confidentiality, construction, real property purchases and leases, third-party equipment leases, research and computer software and hardware); antitrust compliance; trademark

registration and compliance; corporate acquisitions and divestitures; federal and state drug rebate laws; and miscellaneous tax and customs matters. Direct supervisory responsibility for 2 attorneys and indirect responsibility over a trademark assistant and a corporate legal assistant while head of Corporate Law Section.

- Lead Company counsel in negotiation of agreements relating to the formation of the Warner Wellcome Consumer HealthCare Products joint venture, with approximately \$1 billion in annual U.S. sales.
- Participated in U.S. divestitures of group's worldwide industrial hygiene, pesticide and animal health businesses.
- Lead Company counsel in negotiation of a \$50 million revolving credit and term loan agreement with major banking institution.
- Lead Company counsel in \$23 million purchase of minority partner's interest in biotechnology manufacturing joint venture.
- Lead Company counsel in \$13 million and \$7.5 million real estate purchases of buildings adjacent to Company headquarters.

**WOMBLE, CARLYLE, SANDRIDGE & RICE**, Winston-Salem, NC, Associate **Sept. 1978 – July 1982**

A North Carolina law firm with approximately 50 attorneys during this period.

Areas of practice included term loan and asset-based financing as counsel to major southeastern bank; industrial development bond financing; representation of creditors in state and federal courts and in collection matters generally; and commercial and residential real estate transactions.

#### **OTHER PROFESSIONAL ACTIVITIES**

**OXYGEN BIOTHERAPEUTICS, INC.**, Morrisville, NC **Dec. 2011 – Present**

Member of Board of Directors of biopharmaceutical company traded on Nasdaq focusing on the development of therapies that effectively deliver oxygen to the tissues of the body using a proprietary perfluorocarbon oxygen carrier. Member of the Audit Committee.

**ADHEREX TECHNOLOGIES INC.**, RTP, NC **August 2011 – Present**

Member of Board of Directors of biopharmaceutical company traded on the Toronto Stock Exchange focusing on the development of cancer therapies. Appointed Chairman of the Audit Committee in October 2011.

**AEOLUS PHARMACEUTICALS, INC.**, Mission Viejo, CA **June 2004 – Present**

Member of Board Directors of publicly held pharmaceutical company focusing on the development of small molecule antioxidants for various indications, including as radiation protective agents. Appointed to Audit Committee in July 2004 and as Chairman of the Audit Committee in March 2011.

**THERAPYEDGE, INC.**, Research Triangle Park, NC

**March 2000 – Dec. 2002**

Member of the Board of Directors of a privately owned, software development company to provide computer-based therapeutic decision support in certain disease areas. TherapyEdge, Inc. was spun off from Triangle Pharmaceuticals, Inc. in early 2000. Member of Compensation Committee from December 2000 through December 2002.

**INTER-COMPANY COLLABORATION FOR AIDS DRUG DEVELOPMENT**

**April 1998 – April 2001**

Chairperson of the Legal Committee of the Inter-Company Collaboration for AIDS Drug Development, a consortium of the leading pharmaceutical companies in the area of AIDS drug development.

## **EDUCATION**

Duke University School of Law  
Durham, North Carolina  
J.D. with honors 1978  
Class Rank: Top 10%  
Order of the Coif

Harvard College  
Cambridge, Massachusetts  
A.B. 1975 (Economics)  
*Magna cum laude*

Directors' College Program  
National Association of Corporate Directors  
2006 and 2012

Wellcome Senior Management Forum  
London Business School  
1993

Burroughs Wellcome Management Institute  
University of North Carolina at Chapel Hill  
1987-1988

## **PROFESSIONAL ORGANIZATIONS**

North Carolina State Bar  
North Carolina Bar Association  
National Association of Corporate Directors

## **Claude Nicaise, M. D.**

**319 Redstone Drive, Cheshire Ct 06410**

**Phone: +1-203-272-3213**

**Cellular: +1-203-843-3847**

**Email: [cnicaise01@gmail.com](mailto:cnicaise01@gmail.com)**

**Education** : 1976 : Université Libre de Bruxelles  
Graduate in Medicine  
1981 : Université Libre de Bruxelles  
Postgraduate in Internal Medicine and  
Clinical Oncology

**Languages** : French - English

### **Professional Experience:**

2008 – 2013 Senior Vice-President Strategic Development and Global  
Regulatory Affairs,  
Alexion Pharmaceutical  
Cheshire, CT

2004 – 2008 Vice-President Global Development- Dasatinib Project Leader  
Bristol-Myers Squibb Pharmaceutical Research Institute  
Wallingford, CT

2001 – 2004 : Vice-President Worldwide Regulatory Science, Global  
Regulatory Strategy,  
Bristol-Myers Squibb Pharmaceutical Research Institute  
Wallingford, CT

2000 – 2001 Vice-President Worldwide Regulatory Science and Strategy  
Oncology, Infectious Disease and NeuroScience,  
Bristol-Myers Squibb Pharmaceutical Research Institute  
Wallingford, CT

1992 - 1999 : Executive Director Infectious Diseases Clinical Research  
Bristol-Myers Squibb Pharmaceutical Research Institute  
Wallingford, CT

1984 - 1992 : Director Clinical Cancer Research  
Bristol-Myers Pharmaceutical Research and Development  
Wallingford, CT

1983 - 1984 : Medical Advisor - Oncology

Laboratoire Bristol Benelux Brussels – Belgium

- 1981 - 1982 : Staff Medical Oncologist,  
Hopital Braine l'Alleud Waterloo – Belgium
- 1978 - 1981 : Oncology Fellow  
Institut Jules Bordet Brussels – Belgium
- 1977 - 1978 : Resident Internal Medicine  
Hopital Braine l'Alleud Waterloo - Belgium
- 1976 - 1977 : Resident Internal Medicine  
I.M.C. Schaerbeek - Belgium

### **Professional Achievements**

Designed, executed and provided regulatory leadership for the filing and approval of fourteen new molecular entities in various disease area including oncology, infectious disease, virology, neuroscience and rare diseases.

Etoposide (Vepesid®) IV for the treatment of small cell lung cancer (US, 1986)  
Etoposide (Vepesid®) oral for the treatment of small cell lung cancer (US, 1986)  
Ifosfamide (Ifex®) for the treatment of non-small cell lung cancer (US, 1988)  
Mesna (Mesnex®) as a uroprotector for patients treated with ifosfamide (US, 1989)  
Didanosine (Videx®) for the treatment of HIV (Worldwide, 1991)  
Cefepime (Maxipime®) initial filing for the treatment of pneumonia, bronchitis, UTI, skin infections (Worldwide, 1994)  
Cefepime (Maxipime®) supplemental indications for the treatment of febrile neutropenia, intra-abdominal infections, pediatric (Worldwide, 1997-1998)  
Cefprosil (Cefzil®) initial filing for the treatment of bronchitis, sinusitis, otitis, skin infections, pharyngitis (Europe, 1994)  
Gatifloxacin (Tequin®) oral for the treatment of pneumonia, bronchitis, sinusitis, skin, UTI, gonorrhea (Worldwide 2000)  
Gatifloxacin (Tequin®) IV (same indications) (Worldwide, 2000)  
Aripiprazole (Abilify®) for the treatment of schizophrenia (Worldwide, 2002)  
Atazanavir (Reyatase®) for the treatment of HIV (Worldwide 2003)  
Cetuximab (Erbix®) for the treatment of colorectal cancer (US, 2004)  
Dasatinib (Sprycel®) for the treatment of CML and PH+ ALL (Worldwide, 2006)  
Eculizumab (Soliris®) for the treatment of PNH (Japan 2010)  
Eculizumab (Soliris®) for the treatment of atypical Hemolytic Uremic Syndrome (Worldwide 2011)

Coordinated and executed the early development programs for small molecules and biologics and provided regulatory leadership for the filing and approval of IND submission in the US as well as CTA submissions in Europe and CTN submissions in Japan

Extensive experience with worldwide Regulatory Authorities including US-FDA, European Medicine Agency, Japan Pharmaceutical and Medical Device Agency as well as numerous national Agencies in Europe, Asia and Latin America. This included coordination, preparation



of supportive documents and conduct of regulatory meetings at all stage of development (pre-IND, end of phase I, end of phase II, pre-NDA/BLA) in the US, central and national scientific advice in Europe, Pediatric Investigation Plan and meeting with local Health Authorities in Asia and Latin America. Preparation, coordination and presentation at Advisory Committee meetings in various FDA Divisions.

**Professional Affiliations:**

1984 - Present	Member, American Society of Clinical Oncology
1984 - Present	Member, American Association Cancer research
1991 - 2008,	Member, European Society for Medical Oncology
1993 - 2002,	Member, American Society for Microbiology
2006 - Present	Member, American Society of Hematology

**Biography:**

62 publications in peer-reviewed journals and 63 abstracts in international meetings (available upon request)

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**(as a member of the EORTC Lung Cancer Working Party)**

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## **ABSTRACTS PRESENTED IN MEETINGS I.**

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**ABSTRACTS PRESENTED IN MEETINGS II**

**(as a Member of the EORTC Lung Cancer Working Party)**

1. Longeval, E., De Jager, R., Libert, P., Michel, J., Thiriaux, J., Kenis, Y., Klastersky, J. EORTC Lung Cancer Working Party (Belgium). Phase II clinical trials of high dose cisdiammine dichloroplatinum (II) - (DDP) with mannitol-induced diuresis in advanced bronchogenic carcinoma. EORTC Symposium on Progress and Perspectives in Lung Cancer Treatment, Brussels, May 1979.
2. Klastersky, J., Sculier, J.P., Weerts, D., and the EORTC Lung Cancer Working Party. Combination chemotherapy with cyclophosphamide, adriamycin and etoposide for small cell carcinoma of the lung (SCLC). Proceedings of the American Society of Clinical Oncology, Vol. 2, 1983; abstract #C-732.
3. Klastersky, J., Sculier, J.P., Debusscher, L., and the EORTC Lung Cancer Working Party. Late intensification in small cell lung cancer: Results of a pilot study. 13th International Congress of Chemotherapy, Vienna, 1983.
4. Sculier, J.P., Klastersky, J., Weerts, D., Mommen, P., and the EORTC Lung Cancer Working Party. Comparative study of high (120 mg/m<sup>2</sup>) versus standard (60 mg/m<sup>2</sup>) dose of cisplatin in combination with etoposide in the treatment of non-small cell bronchogenic carcinoma. 13th International Congress of Chemotherapy, Vienna, 1983.
5. Sculier, J.P., Klastersky, J., Weerts, D., Mommen, P., and the EORTC Lung Cancer Working Party. Combination chemotherapy with cyclophosphamide, adriamycin, etoposide and cisplatin for small cell carcinoma of the lung. 13th International Congress of Chemotherapy, Vienna, 1983.

## **PRESENTATIONS**

1. Combination chemotherapy with cisplatin (CDDP) and VP-16 in non-small cell (NSC) bronchogenic carcinoma. II World Conference on Lung Cancer, Copenhagen, 1980.
2. Therapy of small cell bronchogenic carcinoma with cisplatin, VP-16-213 and adriamycin. European Society for Medical Oncology, Nice, 1982.
3. Combination of chemotherapy with cisplatin, etoposide, and vindesine in non-small cell lung cancer. UICC Conference on Clinical Oncology, Lausanne, 1981.
4. Phase I clinical trial with marcellomycin. Third NCI-EORTC Symposium on New Drugs in Cancer Therapy, Brussels, 1981.
5. Combination chemotherapy with cisplatin, etoposide and adriamycin in small cell bronchogenic carcinoma. First International Symposium on the Podophyllotoxins in Cancer Therapy, Southampton, 1981.
6. Chemotherapy with etoposide and cisplatin in non-small cell bronchogenic carcinoma. First International Symposium on the Podophyllotoxins in Cancer Therapy, Southampton, 1981.
7. Cisplatin (CDDP), etoposide (VP-16) and vindesine (VDA) in non-small cell bronchogenic carcinoma (NSCBC). American Society of Clinical Oncology, 1982.
8. Phase I clinical trial of marcellomycin. American Association for Cancer Research, 1982.
9. Phase II trial with a combination of dacarbazine (DTIC) and mitomycin C (MMC) in advanced colorectal cancer. European Society for Medical Oncology, 1982.
10. Percutaneous subclavian vein placement of the broviac catheter. European Society for Medical Oncology, 1982.
11. Phase I trial of marcellomycin with a single dose schedule. European Society for Medical Oncology, 1982.
12. Phase I study of cis-diammine I, 1-cyclobutanedicarboxyplatine platinum II (CBDCA) given on a five-day I.V. schedule. European Society for Medical Oncology, 1982.
13. Phase I clinical trial of carboplatin (CBDCA) administered at a five-day schedule. American Association for Cancer Research, 1983.
14. Phase I clinical trial of carboplatin (CBDCA) administered at a five-day schedule. Fourth International Symposium on Platinum Coordination Complexes in Cancer Chemotherapy, Burlington VT, 1983.
15. Ambulatory use of epidural morphine in cancer patients. Second European Conference on Clinical Oncology, Amsterdam, 1983.
16. Phase I study of carboplatin (CBDCA) at a five-day I.V. schedule. Second European Conference on Clinical Oncology, 1983.



17. Overcoming Drug Resistance: New Developments in Cancer Therapy. University of Pennsylvania, 1990.
18. Surgical adjuvant therapy of colorectal cancer: Review of recent developments. 6th Nagoya International Symposium on Cancer Treatment Nagoya, Japan, 1990.
19. Cefepime as Empiric Monotherapy for the Treatment of Febrile Episodes in Neutropenic Patients. 2nd International Symposium on Febrile Neutropenia, Brussels, Belgium 1995.

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2004 to present

Independent consultant specializing in risk analysis for pharmaceutical clients of oncologic drug acquisition candidates. Activities include analysis and critique of preclinical and early clinical data; determination of likely regulatory path/ strategy including pivotal/ phase 3 clinical trial design; analysis of competitive landscape evolution.

1997-2003

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1992-1997

Vice President Worldwide Phase 4 Clinical Research and Head of Health Economic Research Phase 1-4, Schering Plough Corporation, Kenilworth, NJ.

1990-1991

Senior Director and Head, Pharmaceutical Products Division, Schering-Plough, France.

1985-1989

Schering-Plough International, Kenilworth NJ: various positions in International Marketing, culminating in the position of Senior Director International Marketing Anti-infectives and Oncology Products.

1976-1984

Various positions in Lederle Laboratories, UK, and American Cyanamid, Wayne, NJ, culminating in the position of International Product Manager, anti-cancer products, Wayne NJ.

1973-1976

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Onco-Urology for the European Association of Urology
- 2/98-99 Consultant, Medical Oncology  
Regional General Hospital F. Miulli  
Acqua Viva Della Fonti  
Bari, Italy
- 3/98- Faculty Member, Educational Committee of  
the European Society of Medical Oncology (ESMO)
- 8/00- Medical Oncology  
Vincenzo Pansadoro Foundation  
Clinic Pio XI  
Rome, Italy

- 10/00-6/02 Member  
New Treatment Committee of the EORTC
- 3/01- Consultant Physician,  
Medical Oncology Research  
Department of Urology  
Lahey Clinic  
Burlington, Massachusetts, USA
- 3/02- Adjunct Professor of Urology & Urologic Oncology  
Tuft's University School of Medicine, and Lahey Clinic  
Boston, Massachusetts, USA
- 7/02-7/03 Assistant Attending Professor of Medicine  
Department of Medicine  
Medical Oncology  
Columbia Presbyterian Hspital  
New York, New York, USA
- 9/02- Chairman, Department of Medical Oncology  
San Camillo and Forlanini Hospitals  
Rome, Italy
- 3/03-06 Elected Board Member of the EORTC
- 9/03-12/13 Member, Ethical Committee  
San Camillo Forlanini Hospital  
Rome, Italy
- 3/04-08 Member, Protocol Review Committee of the EORTC
- 10/04- Member, Clinical Trials Advisory Board UK
- 12/04- President, Samuel and Barbara Sternberg Cancer Research  
Foundation - ONLUS in Italy
- 02/05- Member, UICC TNM Genitourinary Expert Advisory Panel

- 02/05- Professor at La Sapienza University in the Second Faculty of Medicine in the School of Medical Oncology Specialization
- 02/05- Professor at La Sapienza University in the First Faculty of Medicine in the School of Medical Oncology Specialization
- 3/05-9/06 Chairman of the Division of Medical Oncology San Camillo and Forlanini Hospitals, Rome, Italy
- 2005- 2008 ASCO International Affairs Committee Advisory Group
- 9/2006- Vice-Chairman, Department of Internal Medicine  
San Camillo and Forlanini Hospitals  
Rome, Italy
- 2006 - 2011 Coordinator, Genitourinary Oncology Education for the European Society of Medical Oncology (ESMO)
- 2006-2008 Elected Member, Treasurer and Executive Board Member European Organization for Research and Treatment of Cancer (EORTC)
- 2007- Kidney Cancer Association Medical Advisory Board Member
- 2009-2011 Coordinator, Genitourinary Oncology Education for the European Society of Medical Oncology (ESMO)
- 2009-2010 Elected Member of the Nominating Committee of ESMO
- 2009- European School of Oncology (ESO) Task Force Member for Multidisciplinary Approach to Prostate Cancer
- 2009- Chairman of the Scientific Advisory Board of the Columbus Cancer Foundation (CCF)
- 2009-2012 Elected Board Member of the European Organization for Research and Treatment of Cancer (EORTC)
- 2009- Adjunct Professor in the College of Science & Technology

Department of Biology, Temple University, Philadelphia,  
Pennsylvania, USA

- 2011- International Scientific Advisory Board (ISAB) Member,  
Istituto Toscano Tumori (ITT)
- 2011-2014 Elected Nominating Committee for the ESMO President
- 2012- Executive Board of the EORTC Genitourinary Cancer Group
- 2013- Member, International Academic Advisory Council Prostate  
Cancer
- 2013- Member for 3 year term and Track Leader of the Genitourinary  
Cancer Track of the Scientific Program Committee beginning  
on June 5, 2013, for the 2014 ASCO Annual Meeting

**Coordinator Protocols (selected):**

- 2010- European Principal Investigator, Phase II Study of Dovitinib  
(TKI258) in Advanced Urothelial Carcinoma
- 2010- Principal Investigator, A randomized, double-blind, placebo-  
controlled phase III study to evaluate the efficacy and safety of  
pazopanib as adjuvant therapy for subjects with localized or  
locally advanced RCC following nephrectomy
- 2010 - Steering Committee, A Safety and Efficacy Study of Oral MDV3100  
in Chemotherapy-Naive Patients With Progressive Metastatic Prostate  
Cancer (PREVAIL)
- 2010- European Principal Investigator, A Phase 3 Randomized, Double-  
Blind, Placebo-Controlled Study of Tasquinimod in Men with  
Metastatic Castrate-Resistant Prostate Cancer
- 2012- Principal Investigator, Phase II randomized  
comparative trial of TAK-700 (Orteronel) versus  
bicalutamide in metastatic prostate cancer



patients failing 1st line treatment with LHRH agonists for the EORTC

- 2012- Steering Committee, COMIT -1 Study of Cabozantinib (XL184) Versus Prednisone in Men With Metastatic Castration-resistant Prostate Cancer Previously Treated With Docetaxel and Abiraterone or MDV3100
- 2013- Steering Committee, A Randomized multicenter phase II/III trial, comparing early combination of Ra223 and enzalutamide vs. delayed treatment with Ra223 after progression on enzalutamide in asymptomatic or mildly symptomatic chemotherapy naïve castration resistant prostate cancer patients metastatic to bone (M+CRPC) for the EORTC
- 2013- European Principal Investigator, A Multinational, Phase 3, Randomized, Double-Blind, Placebo-Controlled, Efficacy and Safety Study of Enzalutamide in Patients With Nonmetastatic Castration-Resistant Prostate Cancer
- 2013 European Principal Investigator, A three arm randomized open-label Phase II study of radium-223 dichloride 50 kBq/kg versus 80 kBq/kg, and versus 50kBq/kg in an extended dosing schedule in subjects with castration-resistant prostate cancer metastatic to the bone

**Program Chairman (selected):**

- 2004 Chairman, SIU Committee for Neo-Adjuvant and Adjuvant Chemotherapy Guidelines, Honolulu, Hawaii October 2004
- 2004-2005 Chairman Scientific Committee for GU Cancer for the ECCO 13 Meeting Paris, France October 2005
- 2005 Co-Chairman, 4th International Symposium on Genitourinary Cancers, Los Angeles, California
- 2005 Scientific Committee for Genitourinary Cancer for the ESMO Meeting Vienna, Austria

- 2006 ASCO Scientific Program Committee Chairman for the Multidisciplinary ASCO Prostate Cancer Symposium, San Francisco, February 2006
- 2006 Co-Chairman, 5th International Symposium on Genitourinary Cancers, Los Angeles, California, January 2006
- 2006 Scientific Advisory Board, 4th International Symposium Targeted Anticancer Therapy, Amsterdam, March 2006
- 2006 Member ESMO Prostate Cancer Symposium Scientific Steering Committee
- 2006 Member ESMO 2006 Scientific Steering Committee
- 2006-2007 Scientific Committee for GU Cancer for the ECCO 14 Meeting Barcelona, Spain September 2007
- 2006- Task Force Member of the Methodology for the Development of Innovative Cancer Therapies (MDICT)
- 2007 Scientific Advisory Board, 5th International Symposium Targeted Anticancer Therapy, Amsterdam, March 2007
- 2007 ASCO Steering Committee Chairman for Multidisciplinary ASCO Prostate Cancer Symposium, Orlando, Florida February 2007
- 2006-2007 ESMO Sub- Committee Scientific Chariman for ESMO Congress in Stockhom, Sweden September 2008
- 2007 Medical Oncology Scientific Chairman, First ESMO, ESTRO, EAU and EORTC Joint Annual Multidisciplinary Prostate Cancer Meeting: Embracing Excellence in Prostate and Kidney Cancer
- 2008 ASCO Program Committee International Representative for the GU Cancers Symposium, San Francisco, February 2008

- 2008 Scientific Advisory Board, 6th International Symposium Targeted Anticancer Therapy, Washington, March 2008
- 2009 ASCO Program Committee International Representative for the GU Cancers Symposium, Bladder Track Chairman Orlando, Florida February 2009
- 2009 Scientific Advisory Board, 7th International Symposium Targeted Anticancer Therapy, Amsterdam, March 2009
- 2010- Scientific Steering Committee Member SIUrO (Italian Society Oncologic Urology), Rome, June 2010
- 2010 Scientific Advisory Board, 8th International Symposium Targeted Anticancer Therapy, Washington, March 2010
- 2010 European Kidney Cancer Association Scientific Steering Committee, London, England May 7-8, 2010
- 2011 Scientific Advisory Board, 8th International Symposium Targeted Anticancer Therapy, Paris, France March 2011
- 2011 European Kidney Cancer Association Scientific Steering Committee Chairman, Warsaw, Poland, May 6-7, 2011
- 2012 European Kidney Cancer Association Scientific Steering Committee Chairman, Vienna, Austria, May 4-5, 2012
- 2013 European Kidney Cancer Association Scientific Steering Committee Chairman, Budapest, Hungary, May 3-4, 2013
- 2013 Scientific Co-Chairman, ECCO-ESMO-ESTRO Multidisciplinary Cancer Congress Amsterdam, The Netherlands September 27-October 1, 2013
- 2013-2015 Cancer Education Committee for Genitourinary Oncology for the annual ASCO meeting

2013-2014      Scientific Chairman and Track Leader for Genitourinary  
Oncology for the ASCO 2014 meeting

**Licensed Physician:**

<u>Year:</u>	1978	<u>Place of Issue:</u>	New York, U.S.A #134825
	1979		California, U.S.A. #041164
	1991		Rome, Italy
	1995		Vienna, Austria

**Board Certification:**

1979 National Board of Medical Examiners  
1982 American Board of Internal Medicine  
1983 Board Certified in Medical Oncology  
1995 Certified Specialist in Internal Medicine in Austria  
1995 Certified Specialist in Medical Oncology in Austria  
1996 Certified Specialist in Internal Medicine in Italy  
2002 Certified Specialist in Medical Oncology in Italy

**Honors and Awards:**

12/1972      Phi Beta Kappa, University of Pennsylvania

1976-1977      Research Fellowship, Section of Immunology,  
National Institute of Health, Bethesda, Maryland

1989      Fellow of the American College of Physicians

1994      Folke Edsmyr Memorial Award  
Karolinska Institute, Stockholm, Sweden

- 2003 Annual AICR (American International Club of Rome) Community Service Award for Service in Medicine
- 12/200 Grande Ufficiale al Merito della Repubblica Italiana
- 11/2007 Premio Minerva for Scientific Achievement, XVIII Edition for Achievements in Science
- 05/2011 Premio Rosa "*Risultati Ottenuti Senza Aiuti*", Award for Special Achievement, Canova Club, Rome, Italy
- 09/2013 European Society of Medical Oncology: ESMO Award

**Grants:**

- 1988 American Cancer Society Career Development Grant
- 1996 European Community Grant: Standards, Biomeasures and Testing Programme: Measurement of hematogenous micrometastases associated with prostate cancer by RT/PCR and DNA probe detection of prostate specific antigen (PSA) mRNA.
- 2005 Research grant from the ISS (Istituto Superiore della Sanità) on proteomics as sub coordinator with Prof. Enrico Garci
- 2004-2008 AIRC (Italian Association of Cancer Research) Research Grant as sub coordinator on Prostate Cancer

**Scientific and Medical Societies:**

Investigator National Cancer Institute  
 American Association for Cancer Research  
 American Society of Clinical Oncology  
 American College of Physicians (Associate)  
 American Medical Association  
 American Urological Association  
 New York Academy of Sciences

New York State Society of Internal Medicine  
Society of Urologic Oncology  
Society of Basic Urologic Research  
European Society of Medical Oncology  
European Organization for Research and Treatment of Cancer  
European Association of Urology  
European School of Medical Oncology  
Early Clinical Trials Group of the E.O.R.T.C.  
Italian Association of Cancerology  
Italian Association of Medical Oncology  
Italian Society of Oncologic Urology (Scientific Committee)

**Journal Editorial Activities:**

Solid Tumor Editor, Critical Reviews in Hematology and Oncology  
Genitourinary Editor, European Journal of Cancer Associate Editor for  
Oncology Editor, British Journal of Urology, International (until 12/2012)  
Associate Editor for Frontiers in Genitourinary Oncology  
Genitourinary Editor, European Journal of Cancer  
Section Editor, Urologic Oncology  
Editorial Board, Journal of Clinical Oncology (past)  
Editorial Board, European Urology  
Editorial Board, Annals of Oncology  
Editorial Board, Oncology  
Editorial Board, Journal of Clinical Oncology Online  
Editorial Board, Nature Clinical Practice Urology  
Editorial Board, Annual Report on Prostate Diseases, Harvard Medical  
School  
Editorial Board, Supportive and Palliative Cancer Care  
Editorial Board, Update on Cancer Therapeutics  
Editorial Board, Clinical Genitourinary Cancer  
Editorial Board, Oncology Reviews  
Editorial Board, Kidney Cancer Journal International  
Editorial Board, Therapeutics Advances in Urology  
Editorial Board, Prostate Cancer  
Editorial Board, Clinical Investigation  
Editorial Board, Treatment Strategies – Oncology  
Editorial Board, European Oncology and Hematology

Editorial Board, Frontiers in Genitourinary Oncology  
Editorial Board, Acta Urologica  
Opinion Board, OncoCase  
Ambassador, Oncology Central  
Reviewer, New England Journal of Medicine  
Reviewer, Cancer  
Reviewer, British Journal of Cancer  
Reviewer, Journal of Urology  
Reviewer, Forum Trends in Experimental and Clinical Medicine  
Reviewer, Urology

**Grant Reviewer:**

European 6th Framework Program Project Grants

Lance Armstrong Foundation

Italian Association for Research of Cancer (AIRC)

Ministry of the University and Scientific and Technological Research,  
Department of Economic Affairs – Scientific Research Program

2005 - August 2010: National Cancer Research Network UK (Member  
Clinical Trials Advisory and Awards Committee)

**Spoken Languages:**

English (mother-tongue), Italian (fluent), French (scholastic)

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portable tel: 39-335-6953319

**Marital Status:**

Married to Prof. Vito Pansadoro, 2 children (Vincenzo and Tatiana)



### **Textbook Editor:**

1. Co-editor: Vito Pansadoro and Cora N. Sternberg. Il Carcinoma Infiltrante della Vescica. Accademia Nazionale di Medicina: Forum per la Formazione Biomedica. Sezione Urologia. Rome, 1994.
2. Co-editor: Seth Lerner, Mark Schoenberg and Cora N. Sternberg. Comprehensive Textbook on Bladder Cancer. Taylor and Frances. Abington Oxon OX14 4 RN, England, 2006
3. Co-editor: Hein van Poppel , J.J.M.C.H. Delarosette and Cora N. Sternberg. Textbook on Renal Cell Cancer: Diagnosis and Therapy. Springer Verlag London, 2008
4. Co-editor: Seth Lerner, Mark Schoenberg and Cora N. Sternberg. Textbook on Treatment & Management of Bladder Cancer. Informa UK Ltd, 2008
5. Co-editor: Sergio Bracarda and Cora N. Sternberg. Abiraterone in Castration Resistant Prostate Cancer. ACCMED (Accademia Nazionale di Medicina. Forum Service Editor, 2013
6. Co-editor: Seth Lerner, Mark Schoenberg and Cora N. Sternberg. Textbook on Bladder Cancer: Diagnosis and Clinical Management. Wiley, London 2014 (in press)

### **Guest Editor:**

1. Highlights of the Medical and Surgical Management of Prostate Cancer. Critical Rev Oncol Hematol 2002 Aug;43(2).
2. Targeted Therapies in the Treatment of Genitourinary Cancers. Critical Rev Oncol Hematol 2003 Jun;46 (Suppl.1).
3. Current Treatment Strategies in Transitional Cell Carcinoma of the Bladder. Critical Rev Oncol Hematol 2003 Aug;47.

4. Renal Cancer Editor (with Darracott Vaughan and John Fitzpatrick), Special Edition for British Journal of Urology International, Brit J of Urol Int (May 2007)
5. Bladder Cancer Editor (with Seth Lerner), Special Edition for British Journal of Urology International, Brit J of Urol Int (November 2008)
6. Testicular Cancer Editor (with Joel Sheinfeld), Special Edition for British Journal of Urology International, Brit J of Urol Int (November 2009)

### **Publications:**

1. Pinto ER, Damani PM, Sternberg CN, Liedtke AJ: Fine systolic flutterings of the aortic valve as demonstrated by aortic valve echocardiogram. Am Heart J 1978;95:807-808.
2. Sternberg CN, Magill GB, Sordillo PP, Cheng E, Currie VE: Phase II evaluation of M-AMSA 4'-(9-acridinylamino)-methanesulfon-m-anisindide in patients with adenocarcinoma of the pancreas. Am J Clin Oncol 1983;6:459-462.
3. Sternberg CN, Magill BG, Sordillo PP, Cheng E, Kemeny N: Phase II evaluation of metoprine in advanced pancreatic adenocarcinoma. Cancer Treat Rep 1984;68:1053-1054.
4. Mertelsmann R, Welte K, Sternberg C, O'Reilly R, Moore MAS, Clarkson BD, Oettgen HF. Treatment of immunodeficiency with interleukin-2: initial exploration. J Biol Res Mod 1984; 4:483-490.
5. Sternberg CN, Magill GB, Sordillo PP, Cheng E: MIFA III (mitomycin-C, 5-fluorouracil and adriamycin) chemotherapy for advanced adenocarcinoma of the pancreas. Am J Clin Oncol 1984; 7:529-533.
6. Sternberg CN, Cheng E, Sordillo PP: Phase II trial of 1,2-diaminocyclohexane-(-4-carboxyphthalato) platinum (II) (DACCP) in colorectal carcinoma. Am J Clin Oncol 1984; 7:503-505.

7. Sternberg CN, Yagoda A, Scher HI, Watson RC, Ahmed T, Weiselberg LR, Geller N, Hollander PS, Herr HW, Sogani PC, Morse MJ, Whitmore WF: Preliminary results of M-VAC (methotrexate, vinblastine, doxorubicin, and cisplatin) for transitional cell carcinoma of the urothelium. J Urol 1985;133: 403-407.
8. Sternberg CN, Yagoda A: N-methylformamide induced hypophosphatemia. Cancer Treat Rep 1985;69: 343-344.
9. Sternberg CN, Yagoda A, Casper E, Scoppetuolo M, Scher HI: Phase II trial of elliptinium in advanced renal cell carcinoma and carcinoma of the breast. Anticancer Res 1985; 5:415-418.
10. Sternberg C, Kelsen D, Dukeman M, Leichman L, Heelan R: Carboplatin a new platinum analog in the treatment of epidermoid carcinoma of the esophagus. Cancer Treat Rep 1985;69 (11): 1305-1307.
11. Scher HI, Sternberg CN: Chemotherapy of urologic malignancies. Sem Urol 1985;3: 239-280.
12. Ahmed T, Yagoda A, Scher HI, Sternberg CN, Watson RC: Phase II trial of 10 deaza-aminopterin in patients with bladder cancer. Invest New Drugs 1986;4:171-174.
13. Sternberg CN, Yagoda A, Scher HI, Hollander P: Phase II trial of n-methylformamide for advanced renal cell carcinoma. Cancer Treat Rep 1986;70:681-682.
14. Scher HI, Sternberg CN, Heston WD, Watson RC, Niedzwiecki D, Smart T, Hollander P, Yagoda A, and Community Cancer Oncology Program Investigators: Etoposide in prostatic cancer: experimental studies and phase II trial in patients with bidimensionally measurable disease. Cancer Chemother Pharmacol 1986;18:24-25.
15. Kyriazis AA, Kyriazis AP, Sternberg CN, Sloane NJ, Loveless JD: Morphological, biological, biochemical, and karyotypic characteristics of human pancreatic ductal adenocarcinoma capan-2 in tissue culture and the nude mouse. Cancer Res 1986;46: 5810-5815.

16. Sternberg CN, Yagoda A, Bander NJ, Whitmore WF Jr., Huffman JL, Melamed M, Huffman JL, Fanucchi M, Hollander P, Vaughan ED: Phase I/II trial of intravesical methotrexate for superficial bladder tumors. Cancer Chemother Pharmacol 1986;18:265-269.
17. Mittelman A, Magill G, Raymond V, Sternberg CN, Cheng EW, Sordillo PP, Young C: Phase II trial of idarubicin in patients with pancreatic cancer. Cancer Treat Rep 1987;71(6):657-658.
18. Sternberg CN, and Scher HI: Current status of chemotherapy for urothelial tract tumors. Oncol 1987;1:41-49.
19. Sternberg CN, Sordillo PP, Cheng EW, Chuang YJ, Niedzwiecki D: Evaluation of new anticancer agents against human pancreatic carcinomas in nude mice. Am J Clin Oncol 1987;10(3):219-221.
20. Sternberg CN, Yagoda A, Scher HI, Watson RC, Herr HW, Morse MJ, Sogani PC, Vaughan ED, Bander N, Geller N, Fair WF, Whitmore WF Jr: Chemotherapeutic management of invasive bladder carcinoma. 2nd Symposium, Heinrich Warner Stiftung. Eur Urol 1988;14:19-20.
21. Sternberg CN, Yagoda A, Scher HI, Watson RC, Herr HW, Morse MJ, Sogani PC, Vaughan ED, Bander N, Weiselberg LR, Geller N, Hollander PS, Lipperman R, Fair WR, Whitmore WF Jr: M-VAC (methotrexate, vinblastine, doxorubicin and cisplatin) for advanced transitional cell carcinoma of the urothelium. J Urol 1988;139(3):461-469.
22. Scher H, Yagoda A, Herr H, Sternberg CN, Bosl G, Morse M, Sogani P, Watson R, Dershaw D, Reuter V, Geller N, Hollander P, Vaughan ED, Whitmore WF Jr, Fair WR: Neoadjuvant M-VAC (methotrexate, vinblastine, doxorubicin and cisplatin) effect on primary bladder lesions. J Urol 1988;139(3):470-474.
23. Scher H, Yagoda A, Herr H, Sternberg CN, Morse M, Sogani P, Watson, Reuter V, Whitmore WF Jr, Fair WR: Neoadjuvant M-VAC (methotrexate, vinblastine, doxorubicin and cisplatin) for extravesical urinary tract tumors. J Urol 1988;139(3):475-477.

24. Sternberg CN, Magill GB, Cheng EW, Applewhite A, Sordillo PP: Etoposide (VP-16) in the treatment of advanced adenocarcinoma of the pancreas. Am J Clin Oncol 1988;11(2): 172-173.
25. Sternberg CN, Magill GB, Cheng EW, Hollander P: Phase II trial of menogarol in the treatment of advanced adenocarcinoma of the pancreas. Am J Clin Oncol 1988;11(2): 174-176.
26. Gabilove JL, Jakubowski A, Scher H, Sternberg CN, Wong G, Grous J, Yagoda A, Fain K, Clarkson B, Moore MAS, Clarkson B, Oettgen HF, Alton K, Welte K, Souza L: Effect of Granulocyte Colony- Stimulating Factor non neutropenia and associated morbidity due to chemotherapy for transitional-cell carcinoma of the urothelium. N Eng J Med 1988;318(22): 1414-1422.
27. Gabilove JL, Jakubowski A, Scher HI, Sternberg C, Wong G, Grous, J, Yagoda A, Fain K, Clarkson B, Oettgen HF, Alton K, Welte K, Souza L: Phase I study of G-CSF in patients with transitional cell carcinoma of the urothelium. J Clin Invest 1988;82: 1454-1461.
28. Sternberg, CN, Yagoda A, Scher H, Bosl G, Dershaw D, Rosado K, Houston C, Rosenbluth R, Vinciguerra V, Boselli B, Clinical Community Oncology Program. Phase II trial of trimetrexate in patients with advanced renal cell carcinoma. Eur J Cancer Clin Oncol 1989;25:753-754.
29. Scher HI, Herr HW, Sternberg CN, Bosl G, Morse MJ, Sogani P, Watson RC, Dershaw DD, Reuter V, Curley T, Vaughan ED, Whitmore WF Jr, Fair W, Yagoda A: Neo-adjuvant M-VAC chemotherapy for invasive bladder cancer: Experience with the M-VAC regimen. Brit J Urol 1989;64:250-256.
30. Sternberg CN, Yagoda A, Scher HI, Watson RC, Geller N, Herr HW, Morse MJ, Sogani PC, Vaughan ED, Bander N, Weiselberg L, Rosado K, Smart-Curly T, Lin S, Penenberg D, Fair W, Whitmore WF Jr: M-VAC for advanced transitional cell carcinoma of the urothelium: Efficacy and patterns of response. Cancer 1989;64:2448-2458.
31. Sternberg CN: Chemotherapy in the treatment of advanced urothelial tumors. Der Urologe A 1991;30:33-44.

32. Geller NL, Sternberg CN, Penenberg D, Scher H, Yagoda A. Prognostic factors for survival of patients with advanced urothelial tumors treated with M-VAC chemotherapy. Cancer 1991;67:1525-1531.
33. Pansadoro V, Sternberg CN, DePaula F, Florio, Giannarelli D: A. Transurethral resection of the prostate and metastatic prostate cancer. Cancer 1991;68:1895.
34. Seidman AD, Scher HI, Heinemann MH, Bajorin DF, Sternberg CN, Dershaw DD, Silverberg M, Bosl GJ: Continuous infusion gallium nitrate for patients with advanced refractory urothelial tract tumors. Cancer 1991;68:2561-2565.
35. Sternberg CN: Organ Conservation in T2-3 bladder cancer: the role of transurethral resection, partial cystectomy, and primary and adjuvant chemotherapy. World J Urol 1992;10:2-7.
36. Sternberg CN: Hormone refractory metastatic prostate cancer. Ann Oncol 1992;3(5):331-335.
37. Sternberg C, Arena M, Pansadoro V, D'Agnano I, Calabresi F, De Carli P, Zeuli M, Cancrini A, Rosenkaimer F and Zupi G: Recombinant tumor necrosis factor for superficial bladder tumors. Ann Oncol 1992;3(9):741-745.
38. Arena MG, Sternberg CN, Zeuli M, De Carli P, Cancrini A, Pansadoro V and Calabresi F. Carboplatin and 5-fluorouracil in poor performance status patients with advanced urothelial cancer. Ann Oncol 1993;4(3):241-244.
39. Rosenstein M, Wallner K, Scher H, and Sternberg CN: Treatment of brain metastases from bladder cancer. J Urol 1993;149(3):480-483.
40. Sternberg C, De Mulder P, Van Oosterom A, Fossa S, Giannarelli D, Soedirman J: Escalated M-VAC chemotherapy and recombinant human granulocyte macrophage colony stimulating factor (GM-CSF) in patients with advanced urothelial tract tumors. Ann Oncol 1993;4(5):403-407.

41. Sternberg C, Arena M, Calabresi F, De Carli P, Platania A, Zeuli M, Giannarelli D, Cancrini A, and Pansadoro V: Neo-adjuvant M-VAC (methotrexate, vinblastine, adriamycin and cisplatin) for infiltrating transitional cell carcinoma of the urothelium. Cancer 1993;72(6):1975-1982.
42. Sternberg CN: Adjuvant chemotherapy following radical cystectomy. World J Urol 1993;11(3):169-174.
43. De Mulder PHM, Sternberg CN, van Oosterom AT, Fossa SD: The application of hematopoietic growth factors in advanced transitional cell carcinoma of the urinary tract. Sem Oncol 1994; 21(1)(Suppl 1): 65-69.
44. Sternberg CN, Pansadoro V. The role of systemic chemotherapy for T2-T3 or N+ bladder cancer. Urol International 1994;1(3):5-9.
45. Sternberg CN, Ten Bokkel Huinink WW, Smith JF, Brunsch U, Dirix LY, Pavlidis NA, Franklin H, Wanders J, Le Bail N, Kaye SB: Docetaxel a novel taxoid in the treatment of advanced colorectal carcinoma. Br J Cancer 1994, 70(2):376-379.
46. Pansadoro V, De Paula F, Florio A, and Sternberg CN: Subsequent intravesical treatment in patients who initially fail Bacillus -Calmette Guerin (BCG) therapy. In: Pagano F, Bassi P (eds). BCG Immunotherapy in superficial bladder cancer. Monographs in Urology, Cooperativa Libreria Editrice Universita' di Padova, Padova 1994:147-151.
47. Pansadoro V, De Paula F, Florio A, and Sternberg CN: Major and minor side effects during intravesical therapy with Bacillus Calmette Guerin (BCG). In: Pagano F, Bassi P (eds). BCG Immunotherapy in superficial bladder cancer. Monographs in Urology, Cooperativa Libreria Editrice Universita' di Padova, Padova 1994:185-190.
48. Sternberg CN: The treatment of advanced bladder cancer. Ann Oncol 1995;6 (2):113-126.
49. Sternberg CN, Raghaven D, Ohi Y, Bajorin D, Herr HW, Kato T, Kuroda M, Logothetis C, Scher HI, Splinter TAW, Van Oosterom AT: Neo-

adjuvant and adjuvant chemotherapy in locally advanced disease: What are the effects on survival and prognosis? Int J Urol 1995;2(Suppl 2):76-88.

50. Sternberg CN. Adjuvant and neo-adjuvant chemotherapy of invasive bladder cancer. Eur Urol Update Series 1995;4(4):26-31.
51. Sternberg CN: Bladder preservation: A prospect for patients with urinary bladder cancer. Acta Oncologica 1995;34(5):589-597.
52. Sternberg CN. Multimodal therapy of advanced bladder cancer. Current Opinion in Urol 1995;5(5): 260-266.
53. Verweij J, Catimel G, Sulkes A, Sternberg C, Wolff I, Aamdal S, and van Hoesel Q on behalf of the EORTC Clinical Trials Group and the EORTC Soft Tissue and Bone Sarcoma Group: Phase II studies of Docetaxel in the treatment of various solid tumors. Eur J Cancer 1995;31A (4):S21-S24.
54. Arcangeli G, Micheli A, Verna L, Saracino B, Arcangeli G, Giovinazzo G, D'Angelo L, Pansadoro V, Sternberg CN. Prognostic impact of transurethral resection on patients irradiated for localized prostate cancer. Radiotherapy and Oncology 1995;35(2):123-128.
55. Sternberg CN, Pansadoro V, Lauretti S, Platania A, Giannarelli D, Rossetti A, De Carli P, Arena MG, Cancrini A. Neo-adjuvant M-VAC (methotrexate, vinblastine, adriamycin, and cisplatin) chemotherapy and bladder preservation for muscle infiltrating transitional cell carcinoma of the bladder. Urol Oncology 1995;1(3):127-133.
56. Pansadoro V, Emiliozzi P, Defidio L, Donadio D, Florio A, Maurelli S, Lauretti S, Sternberg CN. Bacillus Calmette Guerin in the treatment of G3T1 transitional cell carcinoma of the bladder: Long-term results. J Urol 1995;154(6):2054-2058.
57. Sternberg CN. Multimodal therapy of advanced bladder cancer. Current Opinion in Urol 1995;5(5):260-266.
58. Sternberg CN: Expert Opinion. Urol Int 1996;3(2):6.
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273. Sternberg CN, Cerbone L, Scher HI, Fizazi K, Saad F, Taplin ME, Miller K, Mulders P, Chi KN, Armstrong AJ, Hirmand M, Selby B, De Bono JS, for the AFFIRM Investigators. Primary, Secondary, and Quality-of-life Endpoint Results

from the Phase 3 AFFIRM Study of Enzalutimide (MDV3100), an Androgen Receptor Signaling Inhibitor. Tumori 2012;Suppl:S138.

274. Mulders P, Fizazi K, Saad F, Sternberg CN, Taplin ME, Miller K, Chi KN, Armstrong AJ, Basch EM, Heidenreich A, Hirmand M, Selby B, de Bono JS, Scher HI, for the AFFIRM Investigators. Enzalutamide, an Androgen Receptor Signaling Inhibitor, Improves Overall Survival, Time to First Skeletal Related Event and Pain. European Multidisciplinary Meeting on Urological Cancers, Barcelona, Spain, November 2012.
275. Eisen T, Sternberg CN, Tomczak P, Harza M, Jinga V, Esteves B, Motzer R. Tivozanib Versus Sorafenib as Initial Targeted Therapy for Patients with Advanced/Metastatic Renal Cell Carcinoma (mRCC): Results from a Phase III Randomized, Open-Label, Multicenter Trial. European Multidisciplinary Meeting on Urological Cancers, Barcelona, Spain, November 2012.
276. Loriot Y, Fizazi K, Scher HI, Saad F, Sternberg CN, Miller K, Mulders P, Chi KN, Hirmand M, Selby B, de Bono JS. Impact of Enzalutamide, an Androgen Receptor (AR) Signalling Inhibitor, on Time to First Skeletal Related Event (SRE) and Pain in the Phase 3 AFFIRM Study. AFU (Association Francaise d'Urologie) Annual Meeting, Paris, November 2012.
277. Saad F, Scher HI, Fizazi K, Mulders P, Taplin ME, Sternberg CN, Miller K, De Wit R, Hirmand M, Selby B, De Bono JS, for the AFFIRM Investigators. Enzalutamide (Formerly MDV3100) Improves Overall Survival in Men with Post-Docetaxel Prostate Cancer Results from the Phase 3 AFFIRM Study. Quebec Urological Association (AUQ), Quebec, November 2012.
278. Sternberg CN. Castration Resistant Prostate Cancer: How Do I Treat It Today and Prospectives for Tomorrow. 10<sup>th</sup> Meeting of the EAU Section of Oncological Urology (ESOU), Rome, January 2013.
279. Sternberg CN. Current Status of Neo-Adjuvant Chemotherapy in Muscle Invasive Bladder Cancer. 10<sup>th</sup> Meeting of the EAU Section of Oncological Urology (ESOU), Rome, January 2013.
280. Sternberg CN, de Bono J, Chi K, Fizazi K, Mulders P, Hirmand M, Selby B, Scher H. Improved Outcomes in Elderly Metastatic Castration-Resistant Prostate Cancer (mCRPC) Patients Treated with the Androgen Receptor Inhibitor

Enzalutamide: Results from the Phase 3 AFFIRM trial. ASCO Genitourinary Cancers Symposium , Orlando, February 2013.

281. Kattan MW, Chakrabarti D, Bhatt K, Mehmud F, Sternberg CN, Motzer RJ. Development and Internal Validation of a Prognostic Nomogram for Overall Survival in Patients with Advanced Renal Cell Carcinoma (Arcc) Treated with Pazopanib (Paz). ASCO Genitourinary Cancers Symposium , Orlando, February 2013.
282. Milowsky M, Dittrich C, Duran I, Jagdev S, Millard F, Sweeney C, Bajorin D, Cerbone L, Dunn R, Sen P, Shi M, Kay A, Squires M, Sternberg CN. Final Results of a Multicenter, Open-Label Phase 2 Trial Of Dovitinib (TKI258) in Advanced Urothelial Carcinoma Patients with Either Mutated or Non-Mutated FGFR3. ASCO Genitourinary Cancers Symposium , Orlando, February 2013. (Abstract # 106458).
283. Pond GR, Agarwal N, Bellmunt J, Choueiri TK, Qu AQ, Fougeray R, Niegisch G, Galsky MD, Wong YN, Stadler WM, Sridhar SS, Sternberg CN, Sonpavde G. Impact of Baseline Prognostic Factors on Progression-Free Survival at 6 Months (PFS6) and Response in Patients Receiving Second-Line Therapy for Advanced Urothelial Carcinoma (UC). ASCO Genitourinary Cancers Symposium , Orlando, February 2013. (Abstract #107472)
284. Halabi S, Lin CY, Small EJ, Armstrong AJ, Kaplan EB, Petrylak DP, Sternberg CN, Shen L, Oudard S, De Bono JS, Sartor AO. A Model for Predicting Overall Survival in Metastatic Castrate-Resistant Prostate Cancer (CRPC) Men Who Failed First Line Chemotherapy. ASCO Genitourinary Cancers Symposium, Orlando, February 2013. (Abstract #107197)
285. Scher H, Fizazi K, Saad F, Chi KN, Taplin ME, Sternberg CN, Armstrong AJ, Hirmand M, Forer D, de Bono JS. Impact of On-Study Corticosteroid Use on Efficacy and Safety in the Phase 3 AFFIRM Study of Enzalutamide (ENZA), an Androgen Receptor Inhibitor. ASCO Genitourinary Cancers Symposium, Orlando, February 2013.
286. Daugaard G, Agerbæk M, Sternberg CN, van Herpen C, Lisa Sengeløv, Collette S, Marreaud S. Phase I Results from a Study of Lapatinib Ditosylate, with Gemcitabine and Cisplatin GC in Metastatic Bladder Cancer. ASCO Genitourinary Cancers Symposium, Orlando, February 2013.



287. Miller K, Scher HI, Fizazi K, Basch EM, Sternberg CN, Hirmand M, Cella D, Ivanescu C, Phung D, Spalding J, Bui Cat N, Holmstrom S, de Bono JS. Effect of Enzalutamide on Health-Related Quality of Life (Hrql) in Men with Metastatic Castration-Resistant Prostate Cancer (mCRPC) Following Docetaxel-Based Therapy: Results from the AFFIRM Study. ASCO Genitourinary Cancers Symposium, Orlando, February 2013. (Abstract #17)
288. Iacovelli R, Milella M, Santoni M, Di Lorenzo G, Ortega C, Sabbatini R, Ricotta R, Lorusso V, Messina C, ATzori F, Zucal PA, Cinieri S, Mosca A, Verzoni E, Primi F, Baratelli C, Cortesi E, Carteni G, Sternberg CN, Procopio G. Prognostic Factors and Validation of Prognostic Nomograms in Patients (Pts) Treated with Three Targeted Therapies (TTS) for Metastatic Renal Cell Carcinoma (mRCC): Results from an Italian Survey. ASCO Genitourinary Cancers Symposium, Orlando, February 2013. (Abstract #470)
289. Sternberg CN, Eisen T, Tomczak P, Strahs A, Esteves B, Berkenblit A, Motzer R. Tivozanib in Patients Treatment-Naïve for Metastatic Renal Cell Carcinoma: A Subset Analysis of the Phase III Tivo-1 Study. Proc Amer Soc Clin Oncol, Chicago, June 2013 (Abstract #4513).
290. Schweizer MT, Huang P, Sternberg CN, De Wit R, Ecstein-Fraisse E, Kattan MW, Kibel AS, Eisenberg MA. Prospective Evaluation of Testosterone (T) Recovery and PSA Relapse Following 18 Months of Androgen Deprivation (ADT) after Prostatectomy (RP): Results from the Tax-3501 Trial. Proc Amer Soc Clin Oncol, Chicago, June 2013. (Abstract #115903)
291. Costa L, Fizazi K, Saad F, Brown JE, von Moos R, Oudard S, Sternberg CN, Ganju V, Miller K, Wang H, Maniar T, Braun A. Denosumab and Zoledronic Acid Treatment in Patients with Genitourinary Cancers and Bone Metastases. Proc Amer Soc Clin Oncol, Chicago, June 2013.
292. George DJ, McGowan T, Daugaard G, Flaig TW, Geczi L, Hotte SJ, Mainwaring PN, Saad F, Smith MR, Souza C, Sternberg CN, Tay MH, Tello Garrido JM, Londhe A, Naini V, Todd MB, Molina A. Interim Safety Results of a Global Early Access Protocol (EAP) of Abiraterone Acetate (AA) in Patients (Pts) with Metastatic Castration-Resistant Prostate Cancer (Mcrpc) Progressing after Taxane-Based Chemotherapy. Proc Amer Soc Clin Oncol, Chicago, June 2013. (Abstract #113212)

293. Halabi S, Lin CY, Small EJ, Armstrong AJ, Kaplan E, Petrylak D, Sternberg CN, Shen L, Oudard S, de Bono J, Sartor O. A Prognostic Model for Predicting Overall Survival in Metastatic Castrate-Resistant Prostate Cancer (mCRPC) Men Treated with Second Line Chemotherapy. Proc Amer Soc Clin Oncol, Chicago, June 2013. (Abstract #110602)
294. Sonpavde G, Russell Pond G, Agarwal N, Choueiri TK, Qu AQ, Fougeray R, Salhi Y, Vaughn DJ, James ND, Niegisch G, Albers P, Galsky MD, Wong YN, Stadler WM, O'Donnell PH, Vogelzang NJ, Sridhar SS, Ko YJ, Sternberg CN, Bellmunt J. Nomogram to Estimate the Activity of Second-Line Therapy for Advanced Urothelial Carcinoma (UC). Proc Amer Soc Clin Oncol, Chicago, June 2013. (Abstract #4524)
295. Ganju V, Costa L, Fizazi K, Saad F, Brown JE, von Moos R, Oudard S, Sternberg CN, Miller K, Wang H, Maniar T, Braun A. Denosumab and Zoledronic Acid (ZA) Treatment in Patients with Genitourinary (GU) Cancers and Bone Metastases. APCC (Australian Prostate Cancer Conference), Melbourne, August 2013.
296. Miller K, Scher HI, Fizazi K, Basch E, Sternberg CN, Hirmand M, Cella D, Ivanescu C, Phung D, Spalding J, Bui Cat N, Holmstrom S, de Bono JS. Enzalutamide Improves Health-Related Quality of Life in Men With Metastatic Castration-Resistant Prostate Cancer Following Docetaxel-Based Therapy: Results From the AFFIRM Study. Société Internationale d'Urologie (SIU), Vancouver, September 2013.
297. Sternberg CN, De Bono JS, Chi KN, Fizazi K, Mulders P, Cerbone L, Hirmand M, Forer D, Scher HI. Improved Outcomes in Elderly Patients with Metastatic Castration-Resistant Prostate Cancer Treated with the Androgen Receptor Inhibitor Enzalutamide: Results from the Phase 3 AFFIRM Trial. Société Internationale d'Urologie (SIU), Vancouver, September 2013.
298. Sternberg CN, Eisen T, Tomczak P, Strahs A, Esteves B, Berkenblit A, Motzer R. Tivozanib in Patients Treatment-Naïve for mRCC Patients in the TIVO-1 Study. German Society of Urology (DGU) Annual Meeting, Dresden, September 2013.
299. Merseburger AS, Scher HI, de Wit R, Bellmunt J, Miller K, Mulders PFA, Stenzl A, Sternberg CN, Fizazi K, Hirmand M, Franks B, Haas GP, de Bono J.

Enzalutamide (ENZA) has Similar Effect in European (EU) and North American (NA) Men Despite Regional Differences in Diagnosis and Treatment: AFFIRM Trial Subanalysis. German Society of Urology (DGU) Annual Meeting, Dresden, September 2013.

300. Scher HI, Fizazi K, Sternberg CN, Armstrong A, Bhattacharya S, Hirmand M, de Bono J. Sensitivity Analyses for Radiographic Progression-Free Survival (rPFS): Results from the Phase 3 Affirm Trial Comparing Enzalutamide to Placebo. Eur J Cancer 2013;Vol 49(Suppl. 2):S684 (Abstract #2864).
301. Sternberg CN, Bracarda S, Carteni G, Lo Re G, Ruggeri EM, Conte P, Kolette Fly Zhang KK, Hariharan S, Camillo Porta C. Sunitinib Expanded-Access Trial in Metastatic Renal Cell Carcinoma (Mrcc) – Final Italian Results. Eur J Cancer 2013;Vol 49(Suppl. 2):S644 (Abstract #2707).
302. Motzer RJ, Szczylik C, Vogelzang NJ, Sternberg CN, Porta C, Zolnierok J, Kollmannsberger C, Rha SY, Bjarnason GA, Melichar B, De Giorgi U, Urbanowitz G, Cai C, Shi M, Escudier B. Phase 3 Trial of Dovitinib vs Sorafenib in Patients with Metastatic Renal Cell Carcinoma after 1 prior VEGF Pathway–Targeted and 1 prior mTOR Inhibitor Therapy. Eur J Cancer 2013;Vol 49(Suppl. 2).
303. Vogelzang N, Petrylak DP, Fizazi K, Sternberg CN, De Wit R, Liu K, Gandhi A, Barton D, Jungnelius U; Fandi A. Analysis of Circulating Tumor Cells (CTCs) in a Phase 3 Study of Docetaxel and Prednisone (DP) with or without Lenalidomide (LEN) in Patients (Pts) with Castrate-Resistant Prostate Cancer (CRPC): The MAINSAIL Trial. Eur J Cancer 2013;Vol 49(Suppl. 2) (LBA # 23)
304. Gore M, Bellmunt J, Eisen T, Escudier B, Mickisch GH, Patard J, Porta C, Ravaud A, Schmidinger M, Schoffski P, Sternberg CN, Szczylik C, Kirpekar S. An Update of the Renal Cancer Appropriateness-Based Treatment Toolkit (Recatt) Based on the Validated Semi-Quantitative RAND UCLA Methodology. Eur J Cancer 2013;Vol 49(Suppl. 2):S645 (Abstract #2709).
305. Escudier B, Porta C, Squires M, Szczylik C, Kollmannsberger C, Melichar, B, Rha SY, Esteban E, Bjarnason GA, Vogelzang N, Sternberg CN, Shi M, Marker M, Motzer RJ. Biomarker Analysis from a Phase 3 Trial (GOLD) of Dovitinib (Dov) vs Sorafenib (Sor) in Patients with Metastatic Renal Cell Carcinoma after 1 Prior VEGF Pathway–Targeted Therapy and 1 Prior Mtor Inhibitor Therapy.

ASCO Genitourinary Cancers Symposium, San Francisco, January-February 2014. (Abstract #473)

306. Kattan MW, Sternberg CN, Mehmud F, Bhatt K, Debasis C, McCann L, Motzer RJ. Development and Validation of a Prognostic Nomogram for Progression-Free and Overall Survival in Patients with Advanced Renal Cell Carcinoma (Arcc) Treated with Pazopanib. ASCO Genitourinary Cancers Symposium, San Francisco, January-February 2014.
307. Beer TM, Armstrong A, Sternberg CN, Higano C, Iversen P, Loriot Y, Rathkopf DE, Bhattacharya S, Carles J, de Bono J, Evans CP, Joshua AM, Kim C, Kumura G, Mainwaring P, Mansbach H, Miller K, Noonberg SB, Venner P, Tombal B. Enzalutamide in Men with Chemotherapy-naïve Metastatic Prostate Cancer (mCRPC): Results of Phase 3 PREVAIL Study. ASCO Genitourinary Cancers Symposium, San Francisco, January-February 2014 (LBA #1).
308. Tombal B, Iversen P, Miller K, Tammela T, Borre M, Bjartell A, Mulders P, Kliment J, Ramon J, Matveev V, Stenzl A, Evans CP, Sternberg CN, Loriot Y, De Bono J, Carles J, Kim CS, Kimura G, Noonberg S, Bhattacharya S, Perabo F, Phung D, Beer TM. Enzalutamide in Men with Chemotherapy-naïve Metastatic Castration Resistant Prostate Cancer (mCRPC): Primary and European Regional Results of the Phase 3 PREVAIL Study. XXIX Annual Congress of the EAU, Stockholm, April 2014.
309. Sternberg CN, Daugaard G, Geczi L, Hotte SJ, Mainwaring PN, Saad F, Souza C, Hiang Tay M, Tello Garrido JM, Galli L, Londhe A, De Porre P, Atlan D, Lee E, McGowan T, Naini V, Todd MB, Molin A, George DJ. Final Analysis of a Large, Open-Label Global Early Access Protocol (EAP) with Abiraterone Acetate (AA) in Patients (Pts) with Metastatic Castration-Resistant Prostate Cancer (mCRPC) Progressing after Chemotherapy. Proc Amer Soc Clin Oncol, Orlando, June 2014. (Abstract # 129933)
310. Hussain M, Fizazi K, Saad F, Shore ND, Heidenreich A, Hirmand M, Perabo F, Khondher Z, Modelska K, Sternberg CN. PROSPER: A Phase 3 Study of Enzalutamide in Non-Metastatic (M0) Castration-Resistant Prostate Cancer (CRPC) Patients. Proc Amer Soc Clin Oncol, Orlando, June 2014. (Abstract #126520)

311. Johnson T, Xu CF, Choueiri TK, Figlin RA, Sternberg CN, King K, Zue Z, Stinnett S, Deen KC, Carpenter C, Spraggs CF, Pandite LN, Motzer RJ. Genome Wide Association Study (GWAS) of Efficacy and Safety Endpoints in Pazopanib or Sunitinib Treated Patients with Renal Cell Carcinoma (RCC). Proc Amer Soc Clin Oncol, Orlando, June 2014.
312. Morris MJ, Loriot Y, Beer TM, Higano CS, Armstrong AJ, Sternberg CN, De Bono JS, Tombal B, Noonberg SB, Mansbach HH, Bhattacharya S, Perabo F, Phung D, Rathkopf DE. Sensitivity Analyses for Radiographic Progression-Free Survival (Rpfs): Results from The Phase 3 Prevail Trial Comparing Enzalutamide to Placebo. Proc Amer Soc Clin Oncol, Orlando, June 2014. (Abstract #128536)
313. Armstrong AJ, Tombal B, Sternberg CN, Higano CS, Rathkopf DE, Loriot Y, Saad F, Joshua AM, De Bono JS, Venna PM, Carles J, Mainwaring PN, Evans CP, Noonberg SB, Mansbach HH, Bhattacharya S, Perabo F, Phung D, Beer TM. Primary, Secondary and Quality-Of-Life Endpoint Results from Prevail, a Phase 3 Study of Enzalutamide in Men with Metastatic Castration Resistant Prostate Cancer (Mcrpc). Proc Amer Soc Clin Oncol, Orlando, June 2014. (Abstract #127316)
314. Sternberg CN, Skoneczna I, Kerst JM, Fossa S, Albers P, Agerbaek M, Dumez H, De Santis M, Theodore C, Leahy M, Chester JD, Verbaeys A, Caty A, Daugaard G, Marreaud S, Cambier S, Sylvester R., for the EORTC GU Cancers Group, GETUG, NCRIBCSG, NCIC and AUO. Final Results of EORTC Intergroup Randomized Phase III Trial Comparing Immediate versus Deferred Chemotherapy after Radical Cystectomy in patients with pT3T4 and/or N+ M0 Transitional Cell Carcinoma (TCC) of the Bladder. Proc Amer Soc Clin Oncol, Orlando, June 2014. (Abstract #130351)
315. Smith MR, De Bono JS, Sternberg CN, Ramies DA, Hessel C, Weitzman AL, Fizazi K. Cabozantinib (Cabo) in Metastatic Castration-Resistant Prostate Cancer (Mcrpc) Patients Previously Treated with Docetaxel and an Androgen Axis-Targeting Agent: Results of the Phase 3 Comet-1 Study. Proc Amer Soc Clin Oncol, Orlando, June 2014. (Abstract #132503)
316. Evans CP, Higano C, Keane T, Andriole, Saad F, Iversen P, Miller K, Choung-Kim S, Kimura G, Armstrong A, Sternberg CN, Loriot Y, De Bono J, Noonberg S, Mansbach H, Bhattacharya S, Perabo F, Beer TM, Tombal B. The PREVAIL Study: Primary and Non-Visceral / Visceral Disease Subgroup Results for

Enzalutamide Treated Men with Metastatic Prostate Cancer (mPC) That Had Progressed on ADT. American Urological Association 2014 (submitted)

317. Sternberg CN, Fizazi K, Saad F, Shore N, Heidenreich A, Hirmand M, Perabo F, Khondher Z, Modelska K, Hussain M PROSPER: A phase 3 study of Enzalutamide in Non-metastatic of enzalutamide in non-metastatic (M0) castration-resistant prostate cancer (CRPC) patients. Eur J Cancer (submitted)

### **Invited Lectures:**

1. Methotrexate (MTX), Vinblastine (VLB), Adriamycin (ADM), and Cisplatin (DDP) (M-VAC) for Transitional Cell Carcinoma (TCC) of the Urothelium.  
American Society of Clinical Oncology  
Toronto, Ontario-Canada  
May 7, 1984
2. Update on the Therapy of Carcinoma of the Bladder and Prostate.  
New York University Medical Center  
New York, New York  
November 9, 1984
3. M-VAC: Methotrexate (MTX), Vinblastine (VLB), Adriamycin (ADM), and Cisplatin (DDP) for Metastatic Transitional Cell Carcinoma (TCC) of the Urothelium.  
American Urological Association  
Atlanta, Georgia  
May 13, 1985
4. Update of Methotrexate (MTX), Vinblastine (VLB), Adriamycin (ADM), and Cisplatin (DDP) for Urothelial Tract Cancer.  
American Society of Clinical Oncology

Houston, Texas  
May 20, 1985

5. Controversies in Urothelial Tract Malignancies.  
Medical Grand Rounds, Memorial Sloan-Kettering Cancer Center  
New York, New York  
July 19, 1985
6. Therapy of Urothelial Malignancies.  
Grand Rounds, Mount Sinai Medical Center  
Department of Neoplastic Diseases  
New York, New York  
September 19, 1985
7. Chemotherapy of Penile Carcinoma.  
Department of Surgery Grand Rounds  
Memorial Sloan-Kettering Cancer Center  
New York, New York  
September 19, 1985
8. Update on Bladder Cancer.  
Community Cancer Center Tumor Board  
Saint Barnabas Medical Center  
Livingston, New Jersey  
October 17, 1985
9. Therapy of Genitourinary Malignancies: Update on M-VAC  
Chemotherapy.  
Fox Chase Cancer Center  
Philadelphia, Pennsylvania  
October 24, 1985
10. Controversies in Urothelial Tract Malignancies.  
Lenox Hill Hospital  
New York, New York  
November 19, 1985
11. Chemotherapy of Bladder Cancer.  
Memorial Sloan-Kettering Cancer Center

Developmental Chemotherapy Service Conference  
New York, New York  
January 28, 1986

12. Surgical Staging and Long Term Survival in Patients with Advanced Transitional Cell Carcinoma (TCC) of the Urothelium Treated with M-VAC. American Society of Clinical Oncology  
Los Angeles, California  
May 5, 1986
13. Controversies in Genitourinary Tract Malignancies.  
Medical Grand Rounds, Brookdale Hospital  
Brooklyn, New York  
June 18, 1986
14. Diagnosis and Therapy of Urothelial Tract Malignancy.  
Medical Grand Rounds, St. Joseph's Medical Center  
Stanford, Connecticut  
June 19, 1986
15. Advances in the Chemotherapy of Advanced Bladder Cancer.  
Hematology-Oncology Tumor Board  
Cornell University, New York Hospital  
New York, New York  
October 20, 1986
16. Controversies in the Treatment of Urothelial Tract Malignancies.  
Combined Staff Tumor Board  
New England Medical Center  
Boston, Massachusetts  
November 14, 1986
17. The M-VAC Regimen for Metastatic Bladder Cancer.  
International Course on Urological Oncology  
Erice, Italy  
December 2, 1986
18. M-VAC Chemotherapy Trials in Transitional Cell Carcinoma: Perspectives for Firstline Chemotherapy.



International Course on Urological Oncology  
Erice, Italy  
December 3, 1986

19. Is Bladder Carcinoma a Chemotherapeutically Responsive Malignancy?  
The London Institute  
London, England  
December 9, 1986

20. Neoadjuvant Chemotherapy and the Management of Urothelial Tract Tumors.  
Combined Staff Conference  
Syracuse University Hospital  
Syracuse, New York  
December 18, 1986

21. Advances in the Treatment of Bladder Cancer.  
Oncology Grand Round, Albert Einstein Medical College  
New York, New York  
February 11, 1987

22. Chemotherapy of Urothelial Tract Tumors in the United States.  
Division of Urology  
Centro Traumatologico Ortopedico Hospital  
Rome, Italy  
February 17, 1987

23. Recent Developments in the Treatment of Urothelial Cancer.  
Oncology Grand Rounds, Stanford Hospital  
Stanford, Connecticut  
March 5, 1987

24. 1) Advances in Bladder Cancer: Chemotherapy M-VAC Regimen.  
2) Advances in Testicular Cancer: Role of Chemotherapy.  
Symposium on Urologic Cancer  
University of Maryland  
Baltimore, Maryland  
April 3, 1987

25. Long Term Survival in Advanced Urothelial Cancer with M-VAC: The First Two Years of Accrual.  
American Society of Clinical Oncology  
Atlanta, Georgia  
May 19, 1987
26. Advances in the Treatment of Bladder Cancer.  
Interdisciplinary Cancer Conference  
Columbia Presbyterian Hospital  
New York, New York  
June 5, 1987
27. Urothelial Tract Tumors: Advances and Future Prospects.  
Emory University School of Medicine  
Winship Cancer Center  
Atlanta, Georgia  
October 9, 1987
28. Chemotherapeutic Management of Invasive Bladder Carcinoma.  
2nd Symposium, Heinrich Warner Stiftung  
Hamburg, Germany  
November 6, 1987
29. M-VAC for Advanced Bladder Cancer.  
Department of Urology  
The Valley Hospital  
Ridgewood, New Jersey  
November 11, 1987
30. Clinical Results, Trends and Strategies in the Treatment of Invasive Bladder Carcinoma at Memorial Sloan Kettering Cancer Center.  
International Symposium of Actual Treatment in Superficial and Invasive Bladder Carcinoma  
Klinikum Grosshadern - University of Munchen Ludwig-Maximilian  
Munich, Germany  
November 21, 1987
31. The Chemotherapeutic Management of Invasive and Metastatic Transitional Cell Carcinoma at Memorial Sloan Kettering Cancer Center.

Division of Medical Oncology  
Johannes Gutenberg - University Klinikum.  
Mainz, Germany  
November 23, 1987

32. Transitional Cell Carcinoma of the Urinary Tract: M-VAC Neoadjuvant Chemotherapy: Memorial Sloan-Kettering Cancer Center Experience.  
Divison of Urology, Department of Surgery  
Long Island Jewish Medical Center  
New Hyde Park, New York  
January 24, 1988
33. Chemotherapy in Urothelial Tract Tumors.  
Multidisciplinary Cancer Conference  
Division of Hematology/Oncology  
The Long Island College Hospital  
Brooklyn, New York  
February 11, 1988
34. Chemotherapeutic Advances in Testicular Cancer.  
Second Symposium on Urologic Cancer  
Department of Surgery  
University of Maryland  
Baltimore, Maryland  
March 25, 1988
35. Management of Disseminated Bladder Cancer.  
Second Symposium on Urologic Cancer  
Department of Surgery  
University of Maryland  
Baltimore, Maryland  
March 25, 1988
36. Advances in Genitourinary Malignancies.  
Yale Univerity  
Department of Oncology  
New Haven, Connecticut  
May 16, 1988

37. Management of Invasive Bladder Cancer.  
Clinical Meetings of "Vecchia Roma"  
St. Giacomo Hospital  
Rome, Italy  
May 30, 1988
38. Chemotherapy of Advanced Carcinoma of the Urothelium.  
The Seventh National Congress ACOI  
Catania, Italy  
June 9, 1988
39. The Use of Tumor Necrosis Factor in Regional Cancer Treatment.  
Boehringer Ingelheim Workshop  
Vienna, Austria  
November 2, 1988.
40. Chemotherapy of Urothelial Carcinoma.  
CTO Hospital  
Division of Urology, Congress of ACOI  
Rome, Italy  
November 19, 1988
41. Future Trends and Prospectives in the Therapy of Carcinoma of the Bladder.  
Division of Urology  
Johannes Gutenberg, University Klinikum  
Mainz, Germany  
December 16, 1988
42. Neo-adjuvant Chemotherapy in the Treatment of Advanced Urothelial Cancer.  
Division of Surgery  
University of Rome, La Sapienza  
Rome, Italy  
April 3, 1989
43. Patterns of Response, Survival and Relapse in Advanced Urothelial Cancer Treated with M-VAC.  
American Society of Clinical Oncology

San Francisco, California

May 23, 1989

44. Biologic and Clinic Aspects of Medical Oncology in the 90's.  
The Italian Association of Medical Oncology  
Rome, Italy  
June 12, 1989
45. Contribution of Chemotherapy in the Treatment of Advanced Bladder Cancer.  
Oncology Data Club, Regina Elena Cancer Institute  
Rome, Italy  
June 22, 1989
46. Adjuvant and Neo-adjuvant Chemotherapy in Metastatic Bladder Cancer.  
25th Anniversary Department of Urology  
Congress New Trends in Urology  
Nijmegen, The Netherlands  
September 13, 1989
47. The M-VAC Experience in the Treatment of Invasive Bladder Cancer.  
The Civic Hospital  
Lugano, Switzerland  
September 21, 1989
48. Neoadjuvant Chemotherapy with M-VAC in Invasive Bladder Tumors.  
VI International Symposium on Urological Oncology.  
Vilamoura, Portugal  
October 27, 1989
49. The Contribution of Chemotherapy in the Treatment of Advanced Bladder Cancer: The M-VAC Experience.  
Annual Meeting of the Regional Section of the Italian Association of Medical Oncology  
University of Modena  
Modena, Italy  
October 31, 1989
50. New Therapeutic Prospectives in the Treatment of Infiltrating Bladder Carcinoma.

The Civil Hospital  
Latina, Italy  
November 11, 1989

51. 1) Chemotherapy Alone and in Association with Conservative Surgery in the Treatment of Invasive Bladder Cancer.  
2) Neo-adjuvant Chemotherapy Experience, Local Response Rates and Survival.  
3) Chemotherapy in Advanced Transitional Cell Carcinoma of the Urothelium.  
Vith Superior Course of Oncology  
Institute of Oncology  
Valencia, Spain  
December 1-2, 1989
52. The Contribution of Chemotherapy in the Treatment of Invasive Urothelial Cancers: Rationale for Adjuvant and Neo-adjuvant Chemotherapy.  
CTO Hospital  
Rome, Italy  
January 26, 1990
53. Systemic Chemotherapy in the Treatment of Bladder Cancer.  
Current Concepts in Urologic Oncology.  
The National Institute for Research and Cure of Tumors, The Senator G. Pascale Foundation  
Naples, Italy  
February 24, 1990
54. Organ Conservation and Reconstructive Surgery in Patients with Advanced Bladder Carcinoma.  
International Course on Urological Oncology  
Erice, Italy  
March 28, 1990
55. Chemotherapeutic Approach in the Treatment of Bladder Cancer.  
Specialization Course of Oncology  
University of Rome, La Sapienza  
Rome, Italy  
April 26, 1990

56. Recombinant Tumor Necrosis Factor in the Treatment of Superficial Bladder Cancer.  
American Association of Cancer Research  
Washington, Washington  
May 25, 1990
57. Intravesical Recombinant Tumor Necrosis Factor (rTNF) in Patients with Superficial Bladder Cancer.  
European Association of Urology  
Amsterdam, The Netherlands  
June 15, 1990
58. Combination Chemotherapy in the Treatment of Advanced Urothelial Tumors: The M-VAC Experience.  
Czech Urological Society  
Prague, Czechoslovakia  
September 15, 1990
59. Bladder Cancer: State of the Art.  
Superior School of Oncology and Biomedical Sciences  
Santa Margherita Ligure, Italy  
October 4, 1990
60. Adjuvant and Neo-adjuvant Chemotherapy in Bladder Cancer.  
International Congress on Debated Problems in Clinical Oncology  
Rome, Italy  
October 12, 1990
61. Intravesical Immuno-and Chemotherapy in the Treatment of Superficial Bladder Cancer.  
International School of Oncology and Experimental Medicine  
Rome, Italy  
October 20, 1990
62. Adjuvant and Neo-adjuvant Chemotherapy in Bladder Cancer.  
Italian Association of Hospital Surgeons (A.C.O.I.) Reunion  
CTO Hospital  
Rome, Italy

October 30, 1990

63. University and Post-Graduate Medical Training in the United States and Italy. Italian Research Group of Clinical Oncology (G.O.I.R.C.)  
Scientific Committee Reunion  
Florence, Italy  
November 9, 1990
64. Metastatic and Locally Invasive Urothelial Cancer: The M-VAC Experience.  
Swiss Association of Clinical Oncology (S.A.K.K.) Meeting  
Lucerne, Switzerland  
November 30, 1990
65. 1) Intravesical Administration of Recombinant Tumor Necrosis Factor (rTNF) in Patients with Superficial Bladder Cancer.  
2) Neo-adjuvant M-VAC (Methotrexate, Vinblastine, Adriamycin and Cisplatin) for Invasive Urothelial Tumors  
XV Congress European Society of Medical Oncology (ESMO)  
Copenhagen, Denmark  
December 2, 1990
66. Chemotherapy for Advanced Bladder Carcinoma.  
Round Table on Current Issues in the Chemotherapy of Urological and Gynecological Cancers  
Copenhagen, Denmark  
December 2, 1990
67. 1) Estramustine and Chemotherapy in the Treatment of Hormone-Resistant Prostate Cancer.  
2) Neo-adjuvant Chemotherapy in the Treatment of Invasive Bladder Cancer and the Possibility of Conservative Surgery.  
3) Strategies and New Approaches in Advanced Transitional Cell Carcinoma of the Urothelium.  
International Urology Course  
Zaragoza, Spain  
February 6, 1991



68. New Therapeutic Prospectives in Bladder Cancer.  
Onco-hematologic Congress on Bladder Carcinoma  
II University of Rome, Tor Vergata and the Saint Eugenio Hospital  
Rome, Italy  
February 16, 1991
69. University and Post-Graduate Medical Training in the United States and Italy.  
Division of Pediatrics  
University of Rome, La Sapienza  
Rome, Italy  
February 19, 1991
70. 1) Controversies in Renal Cell Carcinoma: Adjuvant Hormonal-, Chemo-, and Immunotherapy.  
2) Controversies in Bladder Carcinoma: The Role of Neo-adjuvant Chemotherapy and Adjuvant Chemotherapy.  
3) The Role of Neoplastic Markers in Superficial and Advanced Bladder Tumors.  
2nd International Course of "Oncological Urology"  
Ravenna, Italy  
March 11, 1991
71. State of the Art: Systemic Chemotherapy in Bladder Cancer.  
Nordrhein Westfalische Society of Urology  
Munster, Germany  
April 19, 1991
72. Prognostic Factors of Response, Survival, and Future Trends in the Treatment of Metastatic Bladder Cancer.  
Gustave Roussy Institute  
Paris, France  
June 28, 1991
73. Post Cystectomy Adjuvant Chemotherapy: A Clinical Routine?  
Adjuvant versus Neo-adjuvant Chemotherapy: Advantages and Disadvantages.  
The First International Congress of the Dutch Urological Association

Rotterdam, The Netherlands

October 11, 1991

74. Drug Resistance and Mathematical Modelling in Chemotherapeutic Regimens.  
International School of Oncology and Experimental Medicine  
Rome, Italy  
October 17, 1991
75. State of the Art: Treatment of Infiltrating Bladder Tumors: Prospectives.  
Congress on Immuno-Chemotherapy in Bladder Cancer  
Urological Association of Campana  
Naples, Italy  
November 23, 1991
76. State of the Art: Treatment of Infiltrating Bladder Tumors: Problems and Prospectives.  
Course on Controversies in the Treatment of Urological Tumors  
First Congress of the Italian Oncological Urology Society  
Santa Margherita Ligure, Italy  
November 25, 1991
77. Face to Face: New Trends and Strategies in Bladder Cancer.  
Course on New Trends and Therapeutic Strategies in Medical Oncology  
Superior School of Oncology and Biomedical Sciences  
Santa Margherita Ligure, Italy  
December 5, 1991
78. Primary Chemotherapy in Bladder Cancer: Recent Strategies and Results.  
International Medical and Surgeon's Days  
Turin, Italy  
December 10, 1991
79. Medical Therapies and Treatment of Infiltrating Bladder Carcinoma.  
Course on New Therapeutic Strategies in Breast Cancer and Bladder Carcinoma  
Oncological Center, Hospital USL 23 Arezzo  
Arezzo, Italy  
December 13, 1991

80. Systemic Chemotherapy in Testis Tumors.  
First Urological Winter Forum  
Davos, Switzerland  
February 11, 1992
81. Diagnosis and Treatment of Metastatic and Locally Advanced Bladder Carcinoma: The Memorial Sloan-Kettering Cancer Center Experience.  
Keio University  
Department of Urology  
Tokyo, Japan  
April 20, 1992
82. Experience with Anthracycline Containing Regimens in Advanced Bladder Cancer.  
Japanese Urological Cancer Research Group Meeting  
Nagoya, Japan  
April 24, 1992
83. Experience with M-VAC Chemotherapy in Advanced Transitional Cell Carcinoma.  
Chinese University of Hong Kong  
Prince of Whales Hospital  
Hong Kong, New Territories  
April 28, 1992
84. Clinical and Biological Progress on:
  - 1) Germ Cell Tumors.
  - 2) Bladder Cancer.
  - 3) Renal Cell Carcinoma.
  - 4) Prostate Cancer.Euro-American Conference on Urological Cancer  
Athens, Greece  
September 15-18, 1992
85. Systemic Chemotherapy in Transitional Cell Carcinoma of the Bladder.  
Urologic Tumors: Recent Progress and New Research Objectives  
Conference of the Italian Society of Prevention, Diagnosis and Therapy of Tumors (SIPDTT)

Bologna, Italy  
November 16, 1992

86. 1) Neo-adjuvant M-VAC (methotrexate, vinblastine, adriamycin and cisplatin) for Infiltrating Transitional Cell Carcinoma of the Bladder.  
2) Escalated M-VAC Chemotherapy in Association with GM-CSF in Advanced Urothelial Tumors.  
Second National Congress of the Italian Oncologic Urology Society  
Rome, Italy  
November 25, 1992
87. Neo-adjuvant Chemotherapy in the Treatment of Locally Advanced Bladder Cancer: Orthotopic bladder substitutions.  
Hospital San Giacomo in Augusta, USL Roma 1  
Rome, Italy  
February 11, 1993
88. New Therapeutic Options in the Treatment of Advanced Bladder Carcinoma after M-VAC.  
Italian Association of Medical Oncology  
Regional Section Lazio  
Rome, Italy  
February 13, 1993
89. Second-line Chemotherapy in Urothelial Cancer.  
Symposium on Locally Advanced Bladder Cancer  
Urologic Clinic, Faculty of Medicine RWTH Aachen  
Aachen, Germany  
February 26, 1993
90. Neo-adjuvant Chemotherapy of Invasive Bladder Cancer.  
New Trends in Diagnosis and Treatment of Bladder Cancer  
4th International Symposium on Advances in Urologic Oncology  
San Remo, Italy  
March 19, 1993
91. Neo-adjuvant and Adjuvant Chemotherapy in Locally Advanced Disease: What are the Effects on Survival and Prognosis?  
Fourth International Consensus Meeting on Bladder Cancer

Antwerp, Belgium  
March 24-26, 1993

92. 1) Chemotherapy in Stage I and IIA non Seminomatous Germ Cell Tumors of the Testis.  
2) Neo-adjuvant M-VAC Chemotherapy in Locally Advanced Bladder Cancer.  
Symposium on Adjuvant Therapy in Urological Malignancies  
Vienna, Austria  
April 28-30, 1993
93. Neo-adjuvant M-VAC Chemotherapy for Infiltrating Transitional Cell Carcinoma of the Bladder.  
Annual Meeting American Urological Association  
San Antonio, Texas  
May 17, 1993
94. Neo-adjuvant Chemotherapy in the Treatment of Invasive Bladder Cancer.  
First Meeting of the International Club of Urology  
Capri, Italy  
June 7, 1993
95. Neo-adjuvant and Adjuvant Chemotherapy in the Treatment of Muscle Invasive Bladder Cancer.  
Imperial Cancer Research Fund  
London, England  
June 18, 1993
96. 1) Chemotherapy in Stage I and IIA Non Seminomatous Germ Cell Tumors of the Testis.  
2) Current Status of Neo-adjuvant and Adjuvant Chemotherapy in Locally Advanced Bladder Cancer.  
Aspen Urological Conference  
Aspen, Colorado  
February 6, 1994
97. Chemotherapy: Neo-adjuvant or adjuvant?  
Invasive and Metastatic Bladder Carcinoma  
ACOI Urology 4<sup>o</sup> Interregional Conference

Perugia, Italy  
March 19, 1994

98. Organ Preservation Instead of Cystectomy-a Future Prospect for Patients with Urinary Bladder Cancer  
Folke Edsmyr Memorial Lecture  
Karolinska Institute  
Stockholm, Sweden  
April 15, 1994
99. The Role of Chemotherapy in Advanced Bladder Cancer.  
Duke Comprehensive Cancer Center Second Annual Clinical Cancer Symposium  
Durham, North Carolina  
April 23, 1994
100. Chemotherapy in Metastatic Bladder Cancer.  
Teaching Course  
European Association of Urology  
Berlin, Germany  
July 12, 1994
101. Management of Locally Advanced and Metastatic Prostate Cancer: Chemotherapy-Current Indications and Future  
European Association of Urology  
Berlin, Germany  
July 14, 1994
102. Systemic Chemotherapy in Metastatic Bladder Cancer.  
The Lille Urology Meeting  
Lille, France  
October 14, 1994
103. The Current Status of Chemotherapy for Invasive and Advanced Bladder Cancer.  
44th Annual Meeting of the Central Section of the Japanese Urological Association  
Osaka, Japan  
November 10, 1994

104. Chemotherapy in Invasive Bladder Cancer: Hematopoietic Growth Factors and New Chemotherapeutic Regimens.  
Meeting of the Portugese Genitourinary Group of the E.O.R.T.C.  
Vilamoura, Portugal  
November 19, 1994
105. 1) The Role of Systemic Chemotherapy in Non-metastatic Primary Invasive Bladder Cancer.  
2) Chemotherapy in Prostate Cancer.  
3) New Prognostic Factor Analysis in Seminoma and Non-seminoma.  
4) Chemotherapy in Advanced Seminoma.  
5) Surveillance and Chemotherapy for Low Stage I and II Non-seminoma.  
6) Chemotherapy, Interferon, Interleukin-2 and other Biologic Response Modifiers in Advanced Renal Cell Cancer.  
European School of Medical Oncology  
V Portugese Course of Urologic Oncology  
Vilamoura, Portugal  
November 20-22, 1994
106. 1) Neo-adjuvant and Adjuvant Chemotherapy in Invasive Bladder Cancer.  
2) Systemic Chemotherapy in Advanced Bladder Cancer.  
Residential Course on Infiltrating Bladder Carcinoma.  
National Academy of Medicine, Forum Biomedical Education  
Rome, Italy  
November 24-25, 1994
107. Systemic Chemotherapy in Bladder Cancer.  
Meeting on Bladder Cancer - Regional Oncologic Institute (USL 40)  
Rimini, Italy  
December 2, 1994
108. Bladder Preservation Following Neo-adjuvant Chemotherapy.  
Fifth Meeting of the Italian Club of Oncologic Urology (Cluron)  
Courmayeur, Italy  
January 22, 1995
109. Chemotherapy in Advanced and Infiltrative Bladder Cancer.  
Workshop on Therapy of Urogenital Cancer

Swiss Society for Medical and Pediatric Oncology  
Lausanne, Switzerland  
March 16, 1995

110. Chemotherapy in Metastatic and Infiltrative Bladder Cancer.  
Course for Specialization in Urologic Oncology  
Urologic Institute, University of Padua  
Padua, Italy  
April 6, 1995
111. Neo-adjuvant M-VAC Chemotherapy in Localized Bladder Carcinoma:  
Myth or Reality?  
Annual Meeting of the Euro-American Urological Association  
Porto Cervo, Italy  
June 15, 1995
112. Neo-adjuvant M-VAC Chemotherapy and Bladder Preservation in Locally  
Advanced Bladder Cancer.  
Academic Centre John Radcliffe Hospital  
Oxford, England  
September 1, 1995
113. The Treatment of Metastatic Bladder Cancer and the Role of Neo-adjuvant  
and Adjuvant Chemotherapy.  
Columbia-Presbyterian University Hospital  
Department of Urology Grand Rounds  
New York, New York  
September 21, 1995
114. Diagnosis and Treatment of Bladder Cancer:  
1) Neo-adjuvant Chemotherapy.  
2) Chemotherapy in Advanced Disease.  
14th Annual Meeting of the San Camillo Hospital  
Rome, Italy  
October 12, 1995
115. Neo-adjuvant M-VAC Chemotherapy and Bladder Preservation for Muscle  
Infiltrating Transitional Cell Carcinoma of the Bladder. 8th European  
Conference on Clinical Oncology and Cancer Nursing (ECCO)



Paris, France  
November 2, 1995

116. Neo-adjuvant Chemotherapy in Locally Advanced Bladder Cancer.  
Italian Society Oncological Surgery (S.I.C.O.)  
XIX National Congress  
Florence, Italy  
November 3, 1995
  
117. Neo-Adjuvant Chemotherapy and Bladder Preservation in Infiltrating Bladder Cancer.  
VIth International Urological Update  
University of Madrid Complutense  
Madrid, Spain  
November 6, 1995
  
118. Treatment of Hormonal Independent Prostate Carcinoma.  
Adenoma and Adenocarcinoma of the Prostate  
Urological Congress  
Medical Military School  
Florence, Italy  
December 5, 1995
  
119. Chemotherapy of Hormone-Independent of Prostate Cancer.  
VI Meeting of the Italian Club of Urological Oncology (Cluron)  
Cortina d'Ampezzo, Italy  
January 28, 1996
  
120. Staging and TNM Classification of Prostate Cancer.  
European Association of Urology Group on Guidelines in Onco-Urology  
Paris, France  
February 23, 1996
  
121. 1) Systemic Chemotherapy in Locally Advanced Bladder Cancer: Neo-adjuvant versus Adjuvant Chemotherapy.  
2) Systemic Chemotherapy for Metastatic Bladder Cancer: Indications and Results.  
European Association of Urology  
Budapest, Hungary

March 28, 1996

122. 1) Adjuvant and Neo-Adjuvant Chemotherapy in Bladder Cancer.  
2) Chemotherapy for Metastatic Disease.  
XII National Meeting, Uro-Oncology Group  
Barcellona, Spain  
April 19, 1996
  
123. Adjuvant Chemotherapy in Locally Advanced Bladder Cancer.  
Adjuvant Treatment in Urological Cancer  
International Congress Belgian Society of Urology  
Brussels, Belgium  
May 31, 1996
  
124. Adjuvant Treatment of Breast Cancer.  
Senology Service  
San Raffaele Scientific Institute  
Rome, Italy  
June 6, 1996
  
125. Neo-adjuvant Therapy in Urothelial Cancer.  
Italian Association of Medical Oncology (A.I.O.M.)  
Medical Oncology Course  
Acireale, Italy  
June 17, 1996
  
126. Controversies in Mammographic Screening in Women aged 40-49.  
Senology Service  
San Raffaele Scientific Institute  
Rome, Italy  
June 20, 1996
  
127. Bladder Cancer: The Real Role of Systemic Chemotherapy.  
Advanced Course of Medical Oncology  
European School of Oncology  
Milan, Italy  
September 20, 1996
  
128. 1) Neo-adjuvant Treatment of Invasive Bladder Cancer.

- 2) State of the Art Lecture: Prospects for Organ Preservation in Bladder Cancer.
- 3) Salvage Chemotherapy of Urothelial Malignancies: The E.O.R.T.C. Experience.  
3rd Euro-American Conference on Urological Diseases  
Athens, Greece  
October 11, 1996
129. Salvage Chemotherapy of Urothelial Malignancies.  
Euro-American Urological Association  
Bermuda , USA  
October 19, 1996
130. Hormone Refractory Prostate Cancer: Chemotherapy and Future Prospects  
Prostate Disease Oriented Group of the E.O.R.T.C.  
Autumn Meeting of the E.O.R.T.C.-G.U. Group  
Palermo, Italy  
November 8, 1996
131. 1) Neo-adjuvant Treatment of Invasive Bladder Cancer Prior to Surgery and/or Radiotherapy.  
2) Systemic Chemotherapy for Invasive and Metastatic Bladder Cancer.  
Bladder  
Cancer and Urinary Diversion: Update.  
European Association of Urology, European School of Urology and  
The Slovak Urological Society  
Bratislava, Slovakia  
November 15, 1996
132. Chemotherapy of Bladder Cancer: Adjuvant Therapy and Protocols in Metastatic Disease.  
Urology in Europe  
Urology Institute, University of Milan  
European School of Urology ESU  
Milan, Italy  
November 16, 1996
133. Neo-adjuvant Chemotherapy in Locally Advanced Bladder Cancer.  
Integrated Therapy in Organ Conservation in Oncology

Italian Association of Medical Oncology (A.I.O.M.)  
Latina, Italy  
February 8, 1997

134. Chemotherapy of Urological Tumors.  
Euro-American Urological Association  
Urology in the Third Millennium  
Bari, Italy  
February 13, 1997
135. Neo-adjuvant and Adjuvant Chemotherapy.  
International Course on Urological Innovations  
Cortina, Italy  
February 17, 1997
136. Paclitaxel in the Treatment of Bladder Cancer.  
Clinical Experiences with Paclitaxel  
Naples, Italy  
March 1, 1997
137. Systemic Chemotherapy.  
Urological Hospital Association (A.U.R.O.)  
Bladder Cancer  
Orvieto, Italy  
April 5, 1997
138. Interim Toxicity Analysis of a Randomized Trial in Advanced Urothelial Tract Tumors of High Dose Intensity MVAC Chemotherapy (HD-MVAC) and Recombinant Human Granulocyte Colony Stimulating Factor (G-CSF) Versus Classic MVAC Chemotherapy (E.O.R.T.C. 30924).  
33rd Annual Meeting American Society Clinical Oncology  
Denver, Colorado  
May 20, 1997
139. RT-PCR PSA Simplified.  
International Symposium  
Defining Curability in Prostate Cancer  
The Austrian Society of Urology

June 6, 1997

140. Chemotherapy in the Conservation of the Bladder.  
IV National Congress of the Spanish Society of Oncology  
Leon, Spain  
June 11, 1997
  
141. Gemcitabine: New Therapeutic Treatment in Bladder Cancer  
Gemcitabine: Actual Results and Future Prospectives  
19° National Congress of the Italian Society of Chemotherapy  
Catania, Italy  
June 12, 1997
  
142. Neo-adjuvant M-VAC Chemotherapy and Bladder Sparing.  
Annual Meeting Euro-American Urological Association  
Lisbon, Portugal  
September 25, 1997
  
143. Bladder Tumors.  
Round Table on Organ Preservation in Breast, Head and Neck, Bladder,  
and Rectal Carcinoma  
XV National Meeting of Experimental and Clinical Oncology  
Italian Association of Medical Oncology (A.I.O.M.)  
Cagliari, Italy  
October 5, 1997
  
144. Adjuvant and Neo-adjuvant Chemotherapy of Urothelial Carcinomas.  
Annual Joint Meeting of the German and Austrian Societies for  
Hematology and Oncology  
Linz, Austria  
October 14, 1997
  
145. The Treatment of Bladder Carcinoma: The State of the Art.  
Problems of Clinical Oncology on the Eve of the Year 2000  
Oncological Institute Bari  
Bari, Italy  
April 29, 1998

146. State of the Art in Advanced Bladder Cancer  
1998 Oncology Global Medical Conference  
Indianapolis, Indiana  
May 13, 1998
147. Neo-adjuvant and Adjuvant Chemotherapy in the Treatment of Locally Advanced Bladder Cancer.  
Conservative Treatment of Infiltrating Bladder Tumors  
Parma, Italy  
June 13, 1998
148. 1) Hormone Escaped Prostate Cancer: Is There a Role for Systemic Chemotherapy?  
2) Supportive Treatment of Hormone Escaped Prostate Cancer  
European School of Urology Symposium on Hormone Escaped Prostate Cancer  
St. Petersburg, Russia  
June 20, 1998
149. Chemotherapy in Advanced Bladder Cancer: Are Lives Saved?  
European School of Urology Course  
Lisbon, Portugal  
July 3, 1998
150. Hormone Escaped Prostate Cancer: Treatment Options  
Annual Meeting Euro-American Urological Association  
Paris, France  
September 15, 1998
151. 1) Wait and See versus Adjuvant Chemotherapy in Non Seminomatous Germ Cell Tumor.  
2) Wait and See versus Carboplatin Chemotherapy in Seminoma.  
Workshop on Therapy of Testicular Cancer in Initial Stage and Treatment of Residual Masses  
3) Chemotherapy after Transurethral Resection of the Bladder (TURB).  
Workshop on Integrated Treatment of Infiltrating Bladder Cancer  
8<sup>th</sup> National Congress of the Italian Society of Oncologic Urology (SIUrO)  
Ischia, Italy  
October 5-6, 1998

152. Treatment of Hormone Refractory Prostate Cancer: Chemotherapy and Future Prospects  
1) Prostate Disease Oriented Group of the E.O.R.T.C.  
2) General Assembly of the E.O.R.T.C. G.U. Group  
Autumn Meeting of the E.O.R.T.C. G.U. Group  
Varese, Italy  
October 8, 1998
153. Chemotherapy and Surgery.  
Integrated Treatment in Oncology for Bladder Preservation: Infiltrating Bladder Cancer.  
Italian Association of Oncological Radiotherapy  
Nerola, Italy  
December 11, 1998
154. State of the Art in Advanced Bladder Cancer: Where Are We Now?  
Lilly Oncology Regional Medical Conference and  
European School of Oncology  
Milan, Italy  
February 8, 1999
155. 1) Gemcitabine in Bladder Cancer.  
2) Neoadjuvant Chemotherapy in Bladder Cancer.  
3) Neoadjuvant Antiandrogen Therapy in Prostate Cancer: the European Experience.  
State of the Art in Urology  
Vienna, Austria  
February 12-13, 1999
156. The Medical Treatment of Bladder Cancer.  
Specialization School of Medical Oncology  
University of Verona – Civile Maggiore Hospital Borgo Trento  
Verona, Italy  
March 5, 1999
157. Neo-adjuvant Hormonal Therapy and Radiation Therapy in the Treatment of Locally Advanced Prostate Cancer.

Fourth International Conference on Neo-adjuvant Hormonal Therapy for Prostate Cancer  
Boston, Massachusetts  
March 12, 1999

158. 1) Neo and Adjuvant Chemotherapy for Invasive Bladder Cancer.  
ESU Post Graduate Course on Management and Outcome in Invasive and Locally Advanced Bladder Cancer.  
Annual Meeting European Association of Urology (EAU)  
Stockholm, Sweden  
April 9, 1999
159. New Approaches to Treatment with Gemcitabine.  
Symposium on Management of Advanced Bladder Cancer.  
Annual Meeting European Association of Urology (EAU)  
Stockholm, Sweden  
April 9, 1999
160. Management of advanced bladder cancer: Treatment of Metastatic Disease and Adjuvant Treatment. European School of Urology Course on Bladder and Prostate Cancer (ESU).  
Rostov on Don, Russia  
May 29, 1999
161. Neoadjuvant chemotherapy in Bladder Cancer.  
Symposium on Bladder Cancer.  
XI Advanced Course of Medical Oncology  
European School of Oncology  
Madrid, Spain  
June 11, 1999
162. The Management of Advanced Bladder Cancer.  
Lilly Young Investigator's Meeting  
Indianapolis, Indiana  
June 25, 1999
163. 1) Neo-adjuvant Chemotherapy in Bladder Cancer.  
2) Adjuvant Chemotherapy in Bladder Cancer.  
3) Chemotherapy in Metastatic Bladder Cancer.



Symposium and Training on Bladder Cancer  
Florence, Italy  
July 13, 1999

164. 1) Neo-adjuvant and Adjuvant Chemotherapy: True and False.  
2) Metastatic Bladder Cancer.  
The 3<sup>rd</sup> International Symposium on Bladder Cancer: Invasive Bladder Cancer: The State of the Art  
Padua, Italy  
September 24, 1999
165. 1) Is it Feasible to Preserve the Bladder in Muscle Invasive TCC?  
2) What Are the Limits of Current Chemotherapy Regimens for Bladder Cancer? Are There New Promising Agents?  
3) Approach to the Chemo-Refractory Patient with Metastatic TCC.  
4) State of the Art Lecture: Immunotherapy in Renal Cell Carcinoma.  
5) Hormone Refractory Prostate Cancer: What Are the Current Treatment Options? Secondary Hormone Treatment, Chemotherapy, Vaccines?  
4<sup>th</sup> Ankara Uro-Oncology Course and 1<sup>st</sup> European School Urology (ESU) Uro-Oncology Course  
Ankara, Turkey  
October 2-3, 1999
166. Hormone Refractory Prostate Cancer.  
VI National Congress of the Urological Hospital Association (AURO)  
Palermo, Italy  
October 8, 1999
167. Systemic Treatment of Advanced and Metastatic Disease: State of the Art.  
Adjuvant Chemotherapy in Locally Advanced Bladder Cancer  
Course Director and Teacher in Bladder Cancer Course of the European School of Oncology (ESO)  
Milan, Italy  
October 15-16, 1999
168. Gemcitabine in Bladder Cancer- Moderator and Discussant  
First Congress of the Association of Medical Oncology (AIOM)  
Rome, Italy  
October 26, 1999

169. Bladder Preservation in Locally Advanced Bladder Cancer  
First Congress of the Association of Medical Oncology (AIOM)  
Rome, Italy  
October 28, 1999
  
170. Systemic Therapy of Prostate Cancer: New Strategies  
XV International Course of Urology "Madrid '99"  
(Course of the Spanish Urological Association)  
Madrid, Spain  
October 28-30, 1999
  
171. 1) Hormone Refractory Prostate Cancer  
2) Adjuvant Chemotherapy in Locally Advanced Bladder Cancer  
eURO training - International Symposium on Dilemmas in Bladder and  
Prostate Cancer  
Milan, Italy  
November 4-6, 1999
  
172. The Neo-Adjuvant and Adjuvant Chemotherapy in Bladder Cancer.  
The Chemotherapy in Metastatic Bladder.  
Advanced Course in Oncology  
University of Padua  
Padua, Italy  
January 18, 2000
  
173. The State of the Art of Chemotherapy for Advanced Bladder Cancer  
International Course in Urology  
Cortina D'Ampezzo, Italy  
March 10, 2000
  
174. Chemotherapy in Advanced Prostate Cancer  
Prostate cancer today: International symposium  
Genoa, Italy  
March 28, 2000
  
175. Update in Chemotherapy of Advanced Bladder Cancer  
ESU Post Graduate Course

Brussels, Belgium  
April 14, 2000

176. Neo-Adjuvant Chemotherapy and Bladder Preservation for Muscle-Invasive Bladder Cancer  
XVth Congress of the European Association of Urology  
Brussels, Belgium  
April 15, 2000
177. Can we select Patients for Bladder Preservation based upon Response to Chemotherapy?  
American Urological Association's Annual Meeting 2000  
Atlanta, Georgia  
May 2, 2000
178. Second-line Chemotherapy with every 2-Week Gemcitabine and Paclitaxel in Previously Treated Patients with TCC.  
American Urological Association's Annual Meeting 2000  
Atlanta, Georgia  
May 2, 2000
179. Randomized Phase III Trial in Advanced Urothelial Tract Tumors of High Dose Intensity M-VAC Chemotherapy and G-CSF versus Classic M-VAC  
ASCO  
New Orleans, Louisiana  
May 23, 2000
180. Management of Metastatic Bladder Cancer: New Prospectives with Gemcitabine.  
Tel Aviv, Israel  
September 12, 2000
181. New Chemotherapeutic Strategies in Advanced Transitional Cell Carcinoma.  
Euro American Urological Association's 9<sup>th</sup> Meeting  
Taormina, Italy  
September 30, 2000
182. Chemotherapy in the Management of Advanced Testis Cancer

- 9<sup>th</sup> Course Urology 2000: Yesterday, today, and tomorrow  
Erice, Italy  
November 26, 2000
183. Second-line Chemotherapy in Advanced Bladder Cancer.  
9<sup>th</sup> Course Urology 2000: Yesterday, today, and tomorrow  
Erice, Italy  
November 27, 2000
184. Advances in Treatment of Bladder Cancer in the Year 2000  
Overview 2000: a Year of Oncology  
Milan, Italy  
December 19, 2000
185. Chemotherapy of Bladder Cancer: State of the Art  
Accademia Lancisiana  
Rome, Italy  
January 9, 2001
186. Role of Chemotherapy in Prostate Cancer  
Winter Urologic Forum  
Snowmass, USA  
February 5, 2001
187. Overview of Collaborative Group and International Trials  
The Genolier-Geneva-MSKCC Cancer Conferences  
Prostate Cancer 2001  
Lecturer and Chairman Prostate Cancer 2001  
Geneva, Switzerland  
February 15, 2001
188. Can the Patient with Locally Advanced Disease be Saved?  
ESU Course: Management and Outcome in Invasive Locally Advanced  
Bladder Cancer and Case Presentations  
XVIth Congress of the European Association of Urology  
Geneva, Switzerland  
April 08, 2001
189. M-VAC Neo-Adjuvant Therapy is Not Standard Treatment for Muscle-

Invasive Bladder Cancer  
ASCO Plenary Session  
San Francisco, USA  
May 14, 2001

190. Medical Therapy in Urologic Tumors (State of the Art)  
GUONE  
Controversies in Urologic Oncology  
Desenzano, Italy  
June 22, 2001

191. How Medical Therapy changes in Oncology?  
New Perspectives in the Treatment of Bladder Cancer  
1° Congress in Oncology in the Tuscia Area  
San Martino al Cimino – Viterbo, Italy  
October 5, 2001

192. Systemic Treatment and New Developments in Advanced Prostate Cancer.  
Prostate Cancer Educational Session  
Chairman and Speaker  
Ecco 11  
Lisbon, Portugal  
October 22, 2001

193. Chemotherapy in Organ Preservation in Muscle Invasive Bladder Cancer  
Round Table: Organ Preservation in Bladder Cancer  
Ecco 11  
Lisbon, Portugal  
October 24, 2001

194. Endoscopic Surgery and Bladder Preservation: Possibilities, Limits,  
Perspectives  
Urologic Days A.O. Monaldi  
Naples, Italy  
November 10, 2001

195. Neoadjuvant and Adjuvant Chemotherapy: Which Patients Need it?  
Perspectives in Bladder Cancer  
Monte Carlo

November 17, 2001

196. The Role of Chemotherapy

Round Table: New Concepts and Perspectives on Bladder Preservation for Muscle-Invasive Urothelial Cancer

SIUrO

Milan, Italy

December 4, 2001

197. New Developments in Transitional Cell Carcinoma in 2001

Grandangolo 2001

Milan, Italy

December 18, 2001

198. Retroperitoneal Lymphadenectomy in Testicular Tumors: When and Why?

Laparoscopy in Urology

Bari, Italy

February 9, 2002

199. Chemotherapy for Advanced Stages.

ESU Course: Testicular Cancer

XVIIth Congress of the European Association of Urology

Birmingham, Great Britain

February 24, 2002

200. Neo-adjuvant and Adjuvant Chemotherapy in the Management and Outcome of Invasive and Locally Advanced Bladder Cancer

ESU Course: Management and Outcome in Invasive Locally Advanced Bladder Cancer

XVIIth Congress of the European Association of Urology

Birmingham, Great Britain

February 26, 2002

201. Advanced Bladder Cancer in Patients over 70 Years Old.

V National Conference AIOM

Padua - Albano Terme

March 20, 2002

202. Results of Neoadjuvant and Adjuvant Chemotherapy in Invasive Bladder -

Facts and Fictions  
EORTC GU Group General Assembly  
EORTC Spring Meeting  
Vienna, Austria  
March 23, 2002

203. Advanced Nonseminomatous Germ Cell Tumors  
Diverse Approaches to Chemotherapy  
University of Verona  
Verona, Italy  
April 16, 2002

204. Gemcitabine, Paclitaxel and Other Newer Agents for Locally  
Advanced/Metastatic Transitional Cell Carcinoma  
Targeted Therapies in the Treatment of GU Cancer  
Barcelona, Spain  
April 19, 2002

205. Angiogenesis and Metastasis in GU Cancers  
Session Chairman  
Targeted Therapies in the Treatment of GU Cancer  
Barcelona, Spain  
April 20, 2002

206. Clinical Issues and Future Challenges in the Chemoprevention of Prostate  
and Bladder Cancers  
COX-2 Scientific Advisory Board  
Orlando, USA  
May 17, 2002

207. Future Directions of COX-2 Inhibitors in the Treatment of Prostate and  
Bladder Cancers  
COX-2 Scientific Advisory Board  
Orlando, USA  
May 17, 2002

208. European Initiatives and the Relevance of M-VAC Chemotherapy  
P53/M-VAC Investigators Meeting  
Orlando, USA

May 26, 2002

209. Innovative Therapies in Oncology

New Treatments and Strategies in Urothelial, Prostate, Testis and Kidney Cancers

National Academy of Medicine

Rome, Italy

June 7, 2002

210. Advanced and Invasive Bladder Cancer

Italian Bladder Cancer Study Group

4° GISCAV Meeting

Perugia, Italy

June 15, 2002

211. Treatment Options in Advanced Prostate Cancer

3° International Course in Live Surgery

Bologna, Italy

October 7, 2002

212. Direct from the Pipeline. Results of Phase I and II Studies of New Drugs

7<sup>th</sup> Congress on Progress and Controversies in Oncological Urology VII (PACIOU VII)

Rotterdam, Netherlands

October 12, 2002

213. Treatment Options in Hormone Resistant Prostate Cancer

Educational Session

27<sup>th</sup> ESMO Congress

Nice, France

October 19, 2002

214. Bladder Cancer-State of the Art Today

How to Improve the Outcomes within the Next Years

Educational Session

27<sup>th</sup> ESMO Congress

Nice, France

October 20, 2002



215. Adjuvant Chemotherapy of Bladder Cancer: Is There a Role?  
Challenge Your Expert Session  
Educational Session  
27<sup>th</sup> ESMO Congress  
Nice, France  
October 21 + 22, 2002
216. New Targets for Anticancer Therapy  
EORTC GU Group Autumn Meeting  
Barcelona, Spain  
November 9, 2002
217. Metastatic Renal Cell Cancer Treatments  
Cytokines and Cancer  
European Institute of Healthcare  
Barcelona, Spain  
November 9, 2002
218. Neoadjuvant and Adjuvant Chemotherapy in Urothelial Cancer  
State of the Art in the Management of Urological Malignancies  
Barcelona, Spain  
November 10, 2002
219. Endpoints in Prostate Cancer Clinical Trials  
Prostate Cancer Advisory Board Meeting  
Brussels, Belgium  
November 16, 2002
220. Last Year's Bladder Highlights and Novel Targeted Therapies in Urothelial  
Tumors  
Italian Society of Urologic Oncology  
Florence, Italy  
November 22, 2002
221. Grandangolo: Highlights in Genitourinary Oncology 2002  
Speaker and Chairman  
Genoa, Italy  
December 18, 2002

222. Is Neo-Adjuvant M-VAC Now the Standard for T2-T4 Disease?  
Second Annual Opinion Leader Summit  
Targeted Therapies in the Treatment of Genitourinary Cancers  
St. Thomas, Virgin Islands  
January 17, 2003
223. Breast Cancer. New Biological Drugs  
1° Advanced Oncological Teaching Course  
Tumors in the Elderly  
Bari, Italy  
February 10, 2003
224. Update in the Treatment of Hormone Refractory Prostate Cancer  
Section Meeting of the EORTC GU-Group: Quality in Prostate Cancer  
Diagnosis and Treatment  
XVIIIth European Association of Urology (EAU) Congress  
Madrid, Spain  
March 12, 2003
225. Update on Neoadjuvant and Adjuvant Chemotherapy  
European School of Urology (ESU) Course: Management and Outcome in  
Invasive and Locally Advanced Bladder Cancer.  
XVIIIth EAU Congress  
Madrid, Spain  
March 13, 2003
226. Bladder Sparing and Adjuvant Treatment of Advanced Urethelial Tumours.  
Chairman  
VIIIth European Association of Urology (EAU) Congress  
Madrid, Spain  
March 14, 2003
227. Systemic Chemotherapy in Advanced Bladder Cancer  
Challenge the Expert Session  
XVIIIth European Association of Urology (EAU) Congress  
Madrid, Spain  
March 15, 2003
228. Systemic Chemotherapy in Advanced Bladder Cancer

EORTC Spring Meeting  
Ghent, Belgium  
March 28, 2003

229. Chemotherapy in the Treatment of Prostate Cancer: What is Standard Therapy and What is New?  
Regina Elena Cancer Institute  
Rome, Italy  
April 4, 2003
230. Treatment of Hepatic Metastasis from Colorectal Cancer  
Annual Meeting Roman Society of Surgery  
Rome, Italy  
April 9, 2003
231. Bladder Cancer Chemotherapy – When and Why in 2003?  
Plenary Session- State-of the Art Lecture  
98<sup>th</sup> Annual Meeting American Urological Association  
Chicago, USA  
April 28, 2003
232. Combined Treatment Modalities in Gastric Cancer: How, When and Why?  
Fifth International Gastric Cancer Congress  
Rome, Italy  
May 5, 2003
233. Role of Adjuvant and Neoadjuvant Chemotherapy in Locally Advanced Bladder Cancer  
2003 Oncology Global Medical Conference  
Indianapolis, USA  
May 29, 2003
234. Bcl-2 Targeting in Solid Tumors: Clinical Results  
Direct Targeting of Apoptosis in Cancer Therapy Meeting  
American Society of Clinical Oncology  
Chicago, USA  
May 30, 2003
235. Randomized Phase III Trial of a New Oral Platinum, Satraplatin (JM-216)

plus Prednisone of Prednisone Alone in Patients with Hormone Refractory Prostate Cancer

American Society of Clinical Oncology

Chicago, USA

June 3, 2003

236. Integrated Therapy in Bladder and Pancreas Cancers

Ruolo delle Terapie Integrate nei Tumori Solidi – Incidenza, Prevenzione e Trattamento degli Effetti Collaterali

Genoa, Italy

June 17, 2003

237. Endpoints for Clinical Trials Involving Hormone Refractory Patients

International Symposium on Prostate Cancer. Novel Strategies for a New Disease

Turin, Italy

September 17, 2003

238. Round Table: What is the Role of Urologist, Radiotherapist, Medical Oncologist in the Multimodal Management of Prostate cancer?

International Symposium on Prostate Cancer. Novel Strategies for a New Disease

Turin, Italy

September 17, 2003

239. Docetaxel in the Treatment of Hormone Refractory Prostate Cancer

International Symposium on Prostate Cancer. Novel Strategies for a New Disease

Turin, Italy

September 18, 2003

240. Novel Targets for Prostate Cancer Therapy

International Symposium on Prostate Cancer. Novel Strategies for a New Disease

Turin, Italy

September 18, 2003

241. Satraplatin plus Prednisone vs Placebo plus Prednisone in Patients with Hormone Refractory Prostate Cancer Previously Treated with one Cytotoxic

Chemotherapy Regimen  
European Investigators and Study Coordinators Meeting  
Barcelona, Spain  
September 19, 2003

242. Randomized Phase III Trial of a New Oral Platinum, Satraplatin (JM-216) plus Prednisone or Prednisone Alone in Patients with Hormone Refractory Prostate Cancer  
EORTC Genitourinary Tract Group Protocol # 30972  
European Investigators and Study Coordinators Meeting  
Barcelona, Spain  
September 19, 2003
243. Overview of Chemotherapy in Advanced Bladder Cancer Investigator Meeting  
Rome, Italy  
September 30, 2003
244. Phase II Trial of Gemcitabine and Taxol as Second Line Therapy in Advanced Bladder Cancer Investigator Meeting  
Rome, Italy  
September 30, 2003
245. Phase II Trial of Gemcitabine and Taxol as First Line Therapy in Advanced Bladder Cancer Investigator Meeting  
Rome, Italy  
September 30, 2003
246. Evolving Strategies in the Treatment of Colorectal Cancer  
1<sup>st</sup> Mediterranean Conference on Oncology  
October 7, 2003  
Bari, Italy
247. Chemotherapy of Metastatic Bladder Cancer: State of the Art in 2003  
European American Urological Association: 10<sup>th</sup> Meeting  
October 13, 2003  
Rome, Italy
248. Emerging Strategies in the Therapy of Metastatic Bladder Cancer

State of the Art in 2003  
Vth National Congress in Medical Oncology  
Italian Association of Medical Oncology  
October 21, 2003  
Rome, Italy

249. Satraplatin: A New Anticancer Agent for Prostate Cancer  
CaPCURE 2003 Tenth Annual Scientific Retreat  
November 9, 2003  
New York, USA

250. Chemotherapy in Bladder Cancer: Past, Present and Future  
Treatment Strategies in Bladder Cancer  
January 27, 2004  
Amsterdam, The Netherlands

251. Neoadjuvant and Adjuvant Therapy in Bladder Cancer  
Third International Symposium On Genitourinary Cancers  
February 27, 2004  
Santa Barbara, USA

252. The Management of Advanced Prostate Cancer  
The University of Verona  
March 5, 2004  
Verona, Italy

253. New Developments and Therapeutic Strategies in Advanced Renal Cell  
Cancer  
Regina Elena Cancer Institute  
March 10, 2004  
Rome, Italy

254. Chemotherapy and New Strategies in Bladder Cancer-Neo-Adjuvant,  
Adjuvant and Advanced Cancer  
San Camillo Hospital  
March 17, 2004  
Rome, Italy

255. Adjuvant or Neo-adjuvant Chemotherapy in Locally Advanced Bladder

Cancer  
March 24, 2004  
XIXth Congress of the EAU  
Vienna, Austria

256. Neo-adjuvant Chemotherapy and Adjuvant in Muscle Infiltrating Bladder Cancer

March 25, 2004  
ESU Course in Urology  
XIXth Congress of the EAU  
Vienna, Austria

257. Phase III Activity and Safety of Combination Therapy with Chemotherapy and Biologically Targeted Therapy

April 7, 2004  
Phase III Clinical Trials in Oncology  
Evolving Guidelines and Innovations for Targeted Therapies  
Amsterdam, The Netherlands

258. Bladder Cancer Chemotherapy: When and Why in 2004 and Visiting Professor

April 20, 2004  
University of Leuven, Belgium

259. Treatment of Hormone Prostate Resistant Cancer

May 20, 2004  
10<sup>th</sup> Course Advances and Controversies in Urological Oncology  
Erice, Italy

260. Is There Still a Role for Bladder Preservation?

May 22, 2004  
10<sup>th</sup> Course Advances and Controversies in Urological Oncology  
Erice, Italy

261. Treatment of Metastatic Kidney Cancer

May 22, 2004  
10<sup>th</sup> Course Advances and Controversies in Urological Oncology  
Erice, Italy

262. New Treatments for Metastatic Kidney Cancer  
June 2, 2004  
Challenges in Laparoscopy  
Rome, Italy
263. New Trends in the Treatment of Testis Cancer  
June 3, 2004  
Challenges in Laparoscopy  
Rome, Italy
264. New Treatments in Hormone Refractory Prostate Cancer  
June 4, 2004  
Challenges in Laparoscopy  
Rome, Italy
265. Multidisciplinary Cancer Management Course: Prostate Cancer  
June 6, 2004  
ASCO  
New Orleans
266. Molecular Targeted Therapy in the Treatment of Pancreas Cancer  
June 25, 2004  
VII Congresso Nazionale G.O.I.M.  
Rome, Italy
267. Best of ASCO 2004. Genitourinary Cancer Highlights  
July 10, 2004  
Roswell Park  
Buffalo, New York
268. Chemotherapeutic Advances in the Management of Advanced Bladder Cancer  
September 14, 2004  
Contemporary Issues in Urology  
Dublin, Ireland
269. Chemioterapia e Carcinoma Prostatico: Il Ruolo di Docetaxel  
September 21, 2004  
AIOM



Bologna, Italy

270. Evidence for the Use of Interferon vs High-Dose Interleukin and the Role of Targeted Therapy in Renal Cell Carcinoma  
October 3, 2004  
Global GU Oncology Conference  
SIU International  
Honolulu, Hawaii
271. Management of Recurrent and Advanced Metastatic Prostate Carcinoma  
October 4, 2004  
SIU International  
Honolulu, Hawaii
272. Chemotherapy for Bladder Cancer: Treatment Guidelines for Neo-adjuvant, Adjuvant and Metastatic Cancer  
October 6, 2004  
International Consensus Conference on Bladder Cancer  
Plenary Session  
SIU International  
Honolulu, Hawaii
273. The Emerging Role of Taxanes in Hormone Refractory Prostate Cancer  
October 9, 2004  
The Changing Face of Prostate Cancer Care  
London, UK
274. Chemotherapy in the Management of Localized Bladder Cancer  
October 25, 2004  
ESTRO 23 Congress  
Amsterdam, Netherlands
275. The Role of EGFR Targeted Therapy in Bladder Cancer and the Role of Cytokines in Renal Cell Carcinoma  
29<sup>th</sup> ESMO Congress  
October 30, 2004  
Vienna, Austria
276. Neo-adjuvant and Adjuvant Hormonal Therapy : Who and When?

Diagnosis and Therapy in Localized Prostate Cancer  
November 20, 2004  
Rome, Italy

277. Muscle Invasive and Infiltrative Bladder Cancer  
EAU Guidelines Office Chairmen Meeting  
December 4, 2004  
Rome, Italy

278. Prostate and Renal Cell Cancer Highlights  
Grandangolo 2004  
December 15, 2004  
Genoa, Italy

279. Adjuvant or Neoadjuvant Chemotherapy in Invasive Bladder Cancer?  
National Oncology Meeting ISCO-4  
January 12, 2005  
Eilat, Israel

280. Targeted Therapy in Androgen-independent Prostate Cancer  
National Oncology Meeting ISCO-4  
January 13, 2005  
Eilat, Israel

281. Chemotherapy in Prostate Cancer  
National Oncology Meeting ISCO-4  
January 13, 2005  
Eilat, Israel

282. Ixabepilone (Epothilone analogue) in HRPC  
Ixabepilone in HRPC European Advisory Board  
January 20, 2005  
Paris, France

283. Neo-adjuvant and Adjuvant Chemotherapy in Infiltrative TCC of the  
Bladder Cancer  
2<sup>nd</sup> Meeting of the European Society of Oncological Urology (ESOU)  
January 21, 2005  
Bologna, Italy

284. Early Chemo-hormone Therapy: A new Strategy?  
2<sup>nd</sup> Meeting of the European Society of Oncological Urology (ESOU)  
January 22, 2005  
Bologna, Italy
285. Prostate Cancer: Defining Low, Intermediate, and High Risk Disease  
Chairman  
Fourth International Symposium on Genitourinary Cancers  
January 29, 2005  
Los Angeles
286. Surgical Management of Low Risk Disease  
Chairman  
Fourth International Symposium on Genitourinary Cancers  
January 29, 2005  
Los Angeles
287. Treatment of High Risk Disease with Multi-modality Approaches  
Chairman  
Fourth International Symposium on Genitourinary Cancers  
January 29, 2005  
Los Angeles
288. Next Generation Chemotherapy and Satraplatin Trials  
Fourth International Symposium on Genitourinary Cancers  
January 29, 2005  
Los Angeles, California
289. SU11248: An Oral Multitargeted Tyrosine Kinase Inhibitor with Promising  
Activity in Metastatic Renal Cell Carcinoma  
3<sup>rd</sup> International Symposium on Targeted Anticancer Therapies  
March 4, 2005  
Amsterdam, The Netherlands
290. The Role of Chemotherapy in Metastatic Prostate Cancer  
Plenary Session Lecture  
XXth Congress of the EAU  
March 16, 2005

Istanbul, Turkey

291. Update on Neo-adjuvant and Adjuvant Chemotherapy in Invasive Bladder Cancer  
XXth Congress of the EAU  
European School of Urology Educational Course  
March 18, 2005  
Istanbul, Turkey
  
292. HRPC and Beyond: Treating Prostate Cancer through the Endothelin Axis  
Spotlight on Prostate Cancer  
XXth Congress of the EAU  
March 18, 2005  
Istanbul, Turkey
  
293. New Prospectives in the Chemotherapy of Prostate Cancer  
University of Padua Cancer Center  
April 5, 2005  
Padua, Italy
  
294. Bladder Cancer Highlights ASCO 2005  
ASCO  
May 14, 2005  
Orlando, USA
  
295. Seven Year Update of an EORTC Phase III Trial of High Dose Intensity M-VAC Chemotherapy and G-CSF versus Classic M-VAC in Advanced Urothelial Tract Tumors  
ASCO  
May 16, 2005  
Orlando, USA
  
296. Current Status of Systemic Treatments in Prostate Cancer.  
Adjuvant Prostate Cancer Study 3501 Investigator's Meeting  
June 17, 2005  
New York, USA
  
297. Systemic Therapy in Localized Prostate Cancer Neoadjuvant and Adjuvant  
Sage Prostate Cancer Meeting

June 23, 2005  
Paris, France

298. The Future of RCC with Targeted Therapy  
Worldwide Oncology Forum  
June 25, 2005  
Athens, Greece

299. Multidisciplinary Approaches in Development in Early High Risk Disease  
Adjuvant Prostate Cancer Study 3501 – Investigator’s Meeting  
September 19, 2005  
Paris, France

300. New Molecular Targeted Therapies for RCC  
103<sup>rd</sup> Annual Meeting New York Section, AUA  
September 22, 2005  
Vienna, Austria

301. Systemic Therapies for Prostate Cancer  
103<sup>rd</sup> Annual Meeting New York Section, AUA  
September 23, 2005  
Vienna, Austria

302. What Level of Efficacy and Safety Evidence is Needed for New Agents in  
1st and 2nd Line HRPC ?  
GU Advisory Board Meeting  
October 7, 2005  
Miami, USA

303. New Biological Therapy in Prostate Cancer  
Innovations in Diagnosis and Treatment of Prostate Cancer  
October 14, 2005  
Rome, Italy

304. Genitourinary Cancers: New Biological Drugs and Vaccines  
VII Congresso Nazionale di Oncologia Medica  
October 19, 2005  
Naples, Italy

305. Update on Prostate Cancer  
ECCO 13 – Patients’ Programme  
October 31, 2005  
Paris, France
306. FECS - ECCO 13 Prostate Cancer  
Presidential Session  
ECCO 13  
October 31, 2005  
Paris, France
307. Targeted Therapy in Androgen-Independent Prostate Cancer  
Speaker and Chairman  
ECCO 13  
November 1, 2005  
Paris, France
308. How to Treat Hormone Refractory Prostate Cancer Patients  
Speaker and Chairman  
ECCO 13 – Educational Symposium  
November 3, 2005  
Paris, France
309. HPRC: What has been Accomplished in HPRC, Where Are We Going?  
CECOG Meeting  
November 3, 2005  
Paris, France
310. Chemotherapy of Advanced Disease  
CECOG Meeting  
November 4, 2005  
Paris, France
311. Neo-Adjuvant Chemotherapy in Bladder Cancer  
V Workshop de Urologia Oncologica  
November 19, 2005  
Cavoeiro, Portugal
312. Adjuvant Chemotherapy in Bladder Cancer: Pros and Cons

- V Workshop de Urologia Oncologica  
November 19, 2005  
Cavoeiro, Portugal
313. Targeted Therapy in Advanced Renal Cell Cancer  
V Workshop de Urologia Oncologica  
November 19, 2005  
Cavoeiro, Portugal
314. Clinical Cases in Bladder and Renal Cancer  
Speaker and Chairman  
V Workshop de Urologia Oncologica  
November 19, 2005  
Cavoeiro, Portugal
315. New Molecular Targets for the Therapy of Renal Cancer  
British Association of Urologic Surgery (BAUS)  
Oncology Section  
November 24, 2005  
Edinburgh, United Kingdom
316. Approaches to the Treatment of Hormone Refractory Prostate Cancer  
Symposium on HRPC  
November 30, 2005  
Stockholm, Sweden
317. New Horizons for Treatment of Hormone Refractory Prostate Cancer  
Meet the Professor  
Oncology Institute of Southern Switzerland (OSI)  
December 14, 2005  
Bellinzona, Switzerland
318. Neo-adjuvant Chemotherapy and Cystectomy  
Fifth Multi-disciplinary Symposium on Genitourinary Cancers  
January 27, 2006  
Dana Point, California
319. Neo-adjuvant Chemotherapy and Bladder Preservation - TURB and  
Chemotherapy

Fifth Multi-disciplinary Symposium on Genitourinary Cancers  
January 27, 2006  
Dana Point, California

320. Adjuvant Chemotherapy  
Fifth Multi-disciplinary Symposium on Genitourinary Cancers  
January 27, 2006  
Dana Point, California
321. Hormone Refractory Prostate Cancer - What's Novel?  
Fifth Multi-disciplinary Symposium on Genitourinary Cancers  
January 27, 2006  
Dana Point, California
322. Ketoconazole vs Immuno vs Early Chemotherapy in Prostate Cancer  
Fifth Multi-disciplinary Symposium on Genitourinary Cancers  
January 28, 2006  
Dana Point, California
323. PSA 110 – Symptomatic – Initial Chemotherapy and Second line  
Chemotherapy  
Fifth Multi-disciplinary Symposium on Genitourinary Cancers  
January 28, 2006  
Dana Point, California
324. Novel Agents in Prostate Cancer  
Strategic Advisory Group of Experts in Prostate Cancer  
February 23, 2006  
San Francisco, California
325. Risk Assessment and Staging of Localized Disease  
Co-Chairman  
2006 ASCO Prostate Cancer Symposium - A Multidisciplinary Approach  
February 24, 2006  
San Francisco, California
326. Mentorship/Career Development Lunch for Residents, Fellows, and Junior  
Faculty Mentor  
2006 ASCO Prostate Cancer Symposium - A Multidisciplinary Approach



February 25, 2006  
San Francisco, California

327. Hormone Refractory Prostate Cancer- When and How to Treat?  
Optimizing Systemic Therapy  
2006 ASCO Prostate Cancer Symposium - A Multidisciplinary Approach  
February 26, 2006  
San Francisco, California
328. Indications of Chemotherapy Novel Agents in Hormone Refractory  
Treatment of Prostate Cancer and Targeted Therapies  
ESMO International Symposium (EIS) on Prostate Cancer  
March 11, 2006  
Antwerp, Belgium
329. Promising Agents Targeting Membrane Receptors  
Chairman  
4<sup>th</sup> International Symposium Targeted Anticancer Therapies  
March 17, 2006  
Amsterdam, Netherlands
330. Treatment and Prophylaxis of Cerebral Metastases from Non Small Cell  
Lung Cancer  
Round Table – Moderator  
AIOM  
March 31, 2006  
Rome, Italy
331. Hormone Refractory Prostate Cancer  
Co-Chairman  
XXIth Congress of the EAU  
April 5, 2006  
Paris, France
332. Neoadjuvant and Adjuvant Chemotherapy for Invasive Bladder Cancer  
XXIth Congress of the EAU  
April 6, 2006  
Paris, France

333. Hormone Refractory Prostate Cancer- When and How to Treat?  
XXIth Congress of the EAU  
April 6, 2006  
Paris, France
334. Pazopanib Overview. An Oral, Multi-Target Tyrosine Kinase Inhibitor  
First European International Kidney Cancer Symposium  
April 29, 2006  
Madrid, Spain
335. What's Novel in the Treatment of Hormone Refractory Prostate Cancer  
Prestige Seminars in Oncology  
Institut Jules Bordet  
May 5, 2006  
Brussels, Belgium
336. Front Line and Second Line Therapies  
Education Session: Chemotherapy in the Management of Prostate Cancer  
ASCO Annual Meeting  
June 5, 2006  
Atlanta, USA
337. Medical Management of Prostate and Renal Cancer  
Challenges in Laparoscopy 2006  
June 7, 2006  
Rome, Italy
338. Hormone Refractory Prostate Cancer- When and How to Treat?  
ESMO Multidisciplinary Prostate Cancer Meeting  
September 9, 2006  
Antwerp, Belgium
339. Chemotherapy and Prostate Cancer: Actual State of Developments and  
Future of Chemotherapy in Combined Treatments  
International Advanced Symposium: Laparoscopic Treatment of  
Urological Pelvic Cancers: Prostate and Bladder  
September 16, 2006  
Strasbourg, France

340. Overview of Satraplatin Trials in Hormone Refractory Prostate Cancer  
31<sup>st</sup> ESMO Congress  
September 29, 2006  
Istanbul, Turkey
341. Muscle Invasive and Metastatic Bladder Cancer  
31<sup>st</sup> ESMO Congress  
September 30 and October 1, 2006  
Istanbul, Turkey
342. Ongoing Trials and the Future in Hormone Refractory Prostate Cancer  
Improving Clinical Outcomes in Genitourinary Malignancies: A Focus on  
Prostate and Renal Cancers  
October 6, 2006  
Monte-Carlo, Monaco
343. Biphosphonates in the Treatment of Hormone Refractory Prostate Cancer  
Optimizing Bone Health Management in Patients with Prostate Cancer and  
other Genitourinary Cancers – Advisory Board Meeting  
October 8, 2006  
Monte-Carlo, Monaco
344. Invasive Bladder Cancer: The Best Management – Round Table  
Urology Beyond Boundaries  
October 26, 2006  
Nijmegen, The Netherlands
345. Hormone Refractory Prostate Cancer: Role of the Oncologist  
AUA New York Section Annual Meeting  
October 29, 2006  
New Delhi, India
346. Surgery and Beyond. New Biologic Targeted Therapies in Renal Cell  
Carcinoma  
What is Hot and What is Not!  
AUA New York Section Annual Meeting  
November 4, 2006  
Jaipur, India

347. New Targeted Therapies in Renal Cell Carcinoma  
North Zone Section Meeting of the Urological Society in Jaipur  
November 4, 2006  
Jaipur, India
348. The Management of Hormone Resistant Prostate Cancer  
3<sup>rd</sup> All Ireland Cancer Conference 2006  
November 13, 2006  
Belfast, Ireland
349. Treatment of Hormone Refractory Prostate Cancer and New  
Pharmacological Approaches  
Regina Elena Cancer Institute  
November 24, 2006  
Rome, Italy
350. Moderator, Mesothelioma Session  
Xth National FONICAP Congress  
December 7, 2006  
Rome, Italy
351. Highlights of Bladder and Renal Cancer in 2006  
Grandangolo 2006  
December 18, 2006  
Genoa, Italy
352. Optimizing Treatment Option for Men with Advanced Prostate Cancer  
through a Multidisciplinary Approach  
Symposium Chairman and Speaker  
January 12-13, 2007  
Rome, Italy
353. Chemotherapy for Bladder Cancer  
65<sup>th</sup> Onology Day  
Netherlands Cancer Institute  
January 23, 2007  
Amsterdam, The Netherlands
354. Multicenter randomized EORTC trial 30021 of Docetaxel + Oblimersen and

- Docetaxel in patients (pts) with hormone refractory prostate cancer (HRPC)  
ASCO Prostate Cancer Symposium  
February 23, 2007  
Orlando, USA
355. Targeted Therapy in Hormone Refractory Prostate Cancer  
5<sup>th</sup> International Symposium on Targeted Anticancer Therapies (TAT)  
March 9, 2007  
Amsterdam, The Netherlands
356. When to Give Neo-Adjuvant or Adjuvant Therapy  
EORTC GU-Group Meeting. Translating Results of Clinical Trials into  
Clinical Urological Practice  
XXIIth Congress of the European Association of Urology (EAU)  
March 21, 2007  
Berlin, Germany
357. Neoadjuvant and Adjuvant Chemotherapy for Invasive Bladder Cancer  
ESU Course 13  
XXIIth Congress of the European Association of Urology (EAU)  
March 22, 2007  
Berlin, Germany
358. Optimising Treatment Management of Advanced Prostate Cancer through  
Multidisciplinary Approach.  
Chairman and Speaker  
State of the Art in the Treatment of Hormone Refractory Prostate Cancer  
XXIIth Congress of the European Association of Urology (EAU)  
March 22, 2007  
Berlin, Germany
359. Novel Agents in Metastatic Bladder Cancer  
XIVth National Congress of the Italian Association Medical Oncology  
(AIOM) April 19, 2007  
Pescara, Italy
360. The Contemporary Role of Chemotherapy in Hormone Refractory Prostate  
Cancer  
Austrian Uro-Weekend

April 20, 2007

Rome, Italy

361. Multicenter European Trials in Metastatic Renal Cell Cancer  
The Second European International Kidney Cancer Symposium  
May 5, 2007  
Rome, Italy
  
362. Oral Platinum Analogues in Hormone Refractory Prostate Cancer  
Recent data from Phase III Trials  
43rd American Society of Clinical Oncology (ASCO) Symposium  
June 1, 2007  
Chicago, USA
  
363. Satraplatin Demonstrates Significant Clinical Benefits for the Treatment of  
Patients with HRPC: Results of a Randomized Phase III Trial  
43rd American Society of Clinical Oncology (ASCO)  
June 4, 2007  
Chicago, USA
  
364. A Medical Oncologist's Perspective on the Treatment of Patients with  
Genitourinary Malignancies  
3rd Conference of the World Urologic Oncology Federation (WUOF)  
September 2, 2007  
Paris, France
  
365. Renal Cell Carcinoma: A Critical Appraisal and a Look Forward  
A Second Symposium on Advanced GU Malignancy:  
Optimizing Clinical Outcomes in Prostate and Renal Cell Carcinomas 29<sup>th</sup>  
Congress of the Société Internationale d'Urologie (SIU)  
September 2, 2007  
Paris, France
  
366. What is New in Renal Cancer. Novel Targeted and Signaling Pathway  
Inhibitors - Ongoing Studies  
14<sup>th</sup> European Cancer Conference (ECCO)  
September 24, 2007  
Barcelona, Spain

367. Future Directions in Prevention and Early Detection in Prostate, Lung and Colon Cancer.  
Future Directions in Prevention and Early Detection of Prostate Cancer  
14<sup>th</sup> European Cancer Conference (ECCO)  
September 25, 2007  
Barcelona, Spain
368. Satraplatin Increases PFS and Delays Pain Progression in HRPC: SPARC an International Phase III Trial  
14<sup>th</sup> European Cancer Conference (ECCO)  
September 25, 2007  
Barcelona, Spain
369. Gestione Integrate del Carcinoma Renale Avanzato  
Italian Society of Urology ( SIU)  
September 30, 2007  
Bari, Italy
370. Pazopanib (GW786034) in Advanced/Metastatic Renal Cell Carcinoma  
The Sixth International Kidney Cancer Symposium  
October 13, 2007  
Chicago, USA
371. Advanced Prostate, Bladder and Renal Cancer  
Urology Steering Committee Advisory Board  
October 13, 2007  
Chicago, USA
372. New Options in the Management of Renal Cell Cancer  
EAU 1st Eastern Mediterranean Meeting  
October 19, 2007  
Antalya, Turkey
373. Targeted Therapy in Renal Cell Carcinoma  
Embracing Excellence in Prostate and Kidney Cancer  
1<sup>st</sup> European Multidisciplinary Meeting on Urological Cancer  
November 2, 2007  
Barcelona, Spain

374. Prostate Cancer and Renal Cell Cancer  
Press Conference: Excellence in Multidisciplinary Patient Care  
Embracing Excellence in Prostate and Kidney Cancer  
1<sup>st</sup> European Multidisciplinary Meeting on Urological Cancer  
November 2, 2007  
Barcelona, Spain
375. Update on Hormone Refractory Prostate Cancer Treatment  
World Wide Prostate Cancer Coalition Meeting - WWPCC  
November 3, 2007  
Barcelona, Spain
376. Therapy in Hormone Resistant Prostate Cancer  
Moderator  
Embracing Excellence in Prostate and Kidney Cancer  
1<sup>st</sup> European Multidisciplinary Meeting on Urological Cancer  
November 4, 2007  
Barcelona, Spain
377. Prostate Cancer: What Does the Future Hold?  
Embracing Excellence in Prostate and Kidney Cancer  
1<sup>st</sup> European Multidisciplinary Meeting on Urological Cancer  
November 4, 2007  
Barcelona, Spain
378. Oral Platinum Analogues in Hormone Refractory Prostate Cancer  
XVII Congress Italian Society of Oncologic Urology (SIUrO)  
November 24, 2007  
Modena, Italy
379. Satraplatin in Hormone Refractory Prostate Cancer  
X International Symposium on Platinum Coordination Compounds in  
Cancer Chemotherapy  
November 30, 2007  
Verona, Italy
380. Genitourinary Clinical Cases  
Grandangolo 2007  
December 18, 2007



Genoa, Italy

381. Novel Agents in Castration Resistant Prostate Cancer  
New Options in the Treatment of Urologic Cancers  
January 21, 2008  
Rome, Italy
  
382. Challenges in the Treatment of Advanced Prostate Cancer: Creating a Shared Vision for Optimal Patient Care  
Uro-Oncology Expert Multidisciplinary Workshop  
The World Congress on Controversies in Urology (CURy)  
January 31, 2008  
Barcelona, Spain
  
383. Your Patient, Your Choice: When is the Best Time to Start Chemotherapy?  
Controversies in Advanced Prostate Cancer: The Evolving Role of Chemotherapy  
Plenary Session  
The World Congress on Controversies in Urology (CURy)  
February 2, 2008  
Barcelona, Spain
  
384. Working Together to Achieve Optimal Patient Care  
Panel Discussion  
The World Congress on Controversies in Urology (CURy)  
February 2, 2008  
Barcelona, Spain
  
385. State of the Art/Unmet Needs in Advanced Renal Cancer  
Sage Genitourinary Cancers Meeting  
February 13, 2008  
San Francisco
  
386. Best of Journals Session - Renal Cell Cancer and the AVOREN Study  
Discussant  
The Genitourinary Cancers Symposium  
February 16, 2008  
San Francisco

387. General Session IX: Transitional Science in Renal Cell Cancer  
Co-Chair  
The Genitourinary Cancers Symposium  
February 16, 2008  
San Francisco
388. Chemotherapy and Targeted Therapy in Metastatic Prostate Cancer  
ESU Course 12  
XXIIIth Congress of the European Association of Urology (EAU)  
March 27, 2008  
Milan, Italy
389. Directions in Chemotherapy for Advanced Prostate Cancer:  
Your Team, Your Patient, Your Choice  
XXIIIth Congress of the European Association of Urology (EAU)  
March 27, 2008  
Milan, Italy
390. New Insights in Bladder Cancer  
Meet the Expert Session  
XXIIIth Congress of the European Association of Urology (EAU)  
March 28, 2008  
Milan, Italy
391. Sunitinib Molecular Targeted Therapy in Solid Tumors  
Translation Research in Oncology: Results and prospects  
XVI National Conference in Medical Oncology  
April 11, 2008  
Perugia, Italy
392. Multinodal Treatment of Renal Metastases  
Accademia Lanciaiana  
April 15, 2008  
Rome, Italy
393. New Targets for Treatment of Renal Cell Carcinoma  
Third European International Kidney Cancer Symposium  
May 3, 2008  
Paris, France

394. Safety and Efficacy of Sunitinib in Metastatic Renal Cell Carcinoma: Preliminary Assessment of an Italian Expanded Access Program with Subpopulation Analysis Moderated Poster Session: Kidney Cancer - Evaluation and Treatment  
American Urological Association Annual Meeting  
May 20, 2008  
Orlando, USA
395. Novel Agents and Strategies: What Does the Future Hold?  
Systemic Therapy for Muscle Invasive Bladder Cancer: Who Should Receive Chemotherapy and When  
44<sup>th</sup> Annual Meeting of the American Society of Clinical Oncology (ASCO)  
June 1, 2008  
Chicago, USA
396. Update in Genitourinary Oncology  
Challenges in Laparoscopy & Robotics  
June 7, 2008  
Rome, Italy
397. Translational Research: Fighting The Killers. Prostate Cancer  
Cancer Genotypes and Cancer Phenotypes – Istituto Toscano Tumori  
July 5, 2008  
Florence, Italy
398. Expanding the Boundaries of Clinical Practice: Building on Experience with Targeted Therapies  
Satellite Symposium  
33<sup>rd</sup> ESMO Congress  
September 12, 2008  
Stockholm, Sweden
399. Systemic Chemotherapy and New Experimental Approaches  
Educational Session  
33<sup>rd</sup> ESMO Congress  
September 13, 2008  
Stockholm, Sweden

400. Everolimus (RAD001) vs Placebo after VEGFR-TKI Failure in Metastatic Renal Cell Carcinoma. *Have we raised the bar?*  
33rd ESMO Congress  
September 16, 2008  
Stockholm, Sweden
401. Bladder Preservation in Patients with Muscle Invasive Bladder Cancer  
Congress of the Italian Society of Urology (SIU)  
September 22, 2008  
Rome, Italy
402. Session: Novel Agents on the Horizon  
Moderator  
Kidney Cancer Association Meeting  
September 27, 2008  
Chicago, USA
403. Neoadjuvant and Adjuvant Chemotherapy for Bladder Cancer  
Harvard Urology Oncology Course 2008  
October 3, 2008  
Boston, USA
404. Treatment for Advanced Renal Cell Carcinoma  
Harvard Urology Oncology Course 2008  
October 4, 2008  
Boston, USA
405. Molecular Targeted Therapy for Advanced Disease  
Improving Clinical Outcomes in Genitourinary Malignancy:  
Third Annual Multidisciplinary Symposium  
October 31, 2008  
Paris, France
406. Current Clinical Trials and Future Directions in Advanced Prostate Cancer  
Improving Clinical Outcomes in Genitourinary Malignancy:  
Third Annual Multidisciplinary Symposium  
October 31, 2008  
Paris, France

407. Treatment Options in Renal Cell Carcinoma: What Does the Future Hold?  
Highlights in the Management of Kidney Cancer  
November 8, 2008  
Rome, Italy
408. Systemic Chemotherapy and New Experimental Approaches in Prostate  
Cancer  
November 10/12/13, 2008  
Brisbane, Melbourne, Sydney, Australia
409. High Risk Localized Prostate Cancer  
Trans Tasman Radiation Oncology Group (TROG)  
November 13, 2008  
Sydney, Australia
410. New Therapies in Renal Cell Carcinoma  
Clinical Research at the San Camillo-Forlanini Hospitals  
November 20, 2008  
Rome, Italy
411. Novel Molecular Targeted Therapy  
Diagnostic and Therapeutic Opportunities in Renal Cell Carcinoma  
December 11, 2008  
Rome, Italy
412. Systemic Chemotherapy and New Experimental Approaches in the  
Treatment of Metastatic Prostate Cancer  
European School of Oncology (ESO) E-grandround  
January 22, 2009  
Rome, Italy
413. Challenges in the Treatment of RCC, What's on the Horizon and Beyond?  
Interactive Genitourinary Cancer Conference (IGUCC)  
February 4, 2009  
Lisbon, Portugal
414. Past, Present and Future Chemotherapy Regimens in the Treatment of  
Advanced Bladder Cancer (IGUCC)  
February 4, 2009

Lisbon, Portugal

415. Advances in the Management of Metastatic Renal Cell Cancer  
Controversies in Urology (CURy)  
February 6, 2009  
Lisbon, Portugal
416. Treatment Strategies in Advanced Prostate Cancer/GU Malignancies:  
The Use of Bisphosphonates Across the Continuum  
Controversies in Urology (CURy)  
February 7, 2009  
Lisbon, Portugal
417. Renal Cell Cancer: Sorting the Players  
Promising Agents in Development for Genitourinary Cancers  
SAGE Genitourinary Symposium  
February 25, 2009  
Orlando, USA
418. Pazopanib in Locally Advanced and/or Metastatic Renal Cell Carcinoma:  
Results From a Randomized Phase III Trial (VEG105192)  
Pazopanib European RCC Board  
March 14, 2009  
Rome, Italy
419. Chemotherapy and Targeted Therapies  
European School of Urology (ESU) Course - Metastatic Prostate Cancer  
XXIVth Congress of the European Association of Urology (EAU)  
March 19, 2009  
Stockholm, Sweden
420. Bladder Preservation Debate with Prof. Urs Studer  
Plenary Session 3 – Focus on Bladder Cancer  
XXIVth Congress of the European Association of Urology (EAU)  
March 19, 2009  
Stockholm, Sweden
421. Not another TKI  
Managing Metastatic Disease

4<sup>th</sup> European International Kidney Cancer Symposium  
May 8, 2009  
Berlin, Germany

422. The Oncologist: T3 Prostate Cancer  
Prostate Cancer: Diagnosis and Treatment. An Update  
Urologi Ospedalità Gestione Privata – U.r.O.P.  
May 15, 2009  
Rome, Italy
423. Adjuvant Therapy After Radical Prostatectomy: The Place of Chemotherapy  
Challenges in Laparoscopy & Robotics 2009  
May 25, 2009  
Paris, France
424. Best Practices for the Management of Relapsed / Refractory RCC  
Critical Choices for Improving Outcomes in Renal Cell Carcinoma  
45<sup>th</sup> American Society of Clinical Oncology (ASCO) Symposium  
May 31, 2009  
Orlando
425. Phase III Trial of Pazopanib in Locally Advanced and/or Metastatic Renal  
Cell Carcinoma  
45<sup>th</sup> Annual Meeting of the American Society of Clinical Oncology (ASCO)  
Symposium  
June 1, 2009  
Orlando
426. Novel Therapy in Metastatic RCC  
June 23, 2009  
Tel Aviv, Israel
427. Neo-Adjuvant and Adjuvant Chemotherapy: State of the Art  
Hot Topic on Bladder Cancer  
Società Italiana di Urologia Oncologica (Siuro)  
June 25, 2009  
Milan, Italy
428. Pazopanib: Another TKIs or Therapeutic Breakthrough

Second Pavia International Symposium on Advanced Kidney Cancer  
June 27, 2009  
Pavia, Italy

429. Renal Cell Carcinoma: An Amazing Story of Improved Outcomes  
Satellite Symposium: Exploring New Horizons in Renal Cell Carcinoma and Prostate Cancer  
September 20, 2009  
Berlin, Germany
430. Predictive and prognostic factors in a phase III study of pazopanib in patients with advanced renal cell carcinoma.  
Proffered Paper Session Genitourinary Malignancies  
ECCO 15/34<sup>th</sup> ESMO Multidisciplinary Congress  
September 22, 2009  
Berlin, Germany
431. Future Strategies in the Treatment of mRCC.  
Satellite Symposium: Maximising patient outcomes with targeted agents in mRCC: Current and future strategies  
ECCO 15/34<sup>th</sup> ESMO Multidisciplinary Congress  
September 22, 2009  
Berlin, Germany
432. Moderator in Invited Abstracts Session  
Kidney Cancer Symposium  
September 26, 2009  
Chicago
433. Treatment of Castration Refractory Prostate Cancer: State of the Art and Future Strategies  
AIOM (Italian Association of Medical Oncology)  
October 10, 2009  
Milan, Italy
434. Drugs in the Pipeline  
New Drug Developments in Advanced Prostate Cancer  
EORTC (European Organization for Research and Treatment of Cancer)  
Genitourinary Autumn Meeting



October 15, 2009  
London, Great Britain

435. Novel Agents in Renal Cell Carcinoma  
State of the Art in Urologic Oncology  
Visiting Professor  
October 24, 2009  
Heidelberg, Germany

436. Treatment of Castration Resistant Prostate Cancer  
State of the Art in Urologic Oncology  
Visiting Professor  
October 24, 2009  
Heidelberg, Germany

437. Challenging Cases in Bladder Cancer  
Société Internationale d'Urologie (SIU)  
November 2, 2009  
Shanghai, China

438. Plenary session on Testis Cancer  
Société Internationale d'Urologie (SIU)  
Chemotherapy in the Treatment of Testicular Cancer  
November 4, 2009  
Shanghai, China

439. Targeted Therapy in the Treatment of Prostate Cancer  
Russian Cancer Congress  
November 18, 2009  
Moscow, Russia

440. Genitourinary Cases  
Grandangolo 2009  
December 1, 2009  
Genoa, Italy

441. Prostate Cancer: Systemic Chemotherapy & New Experimental Approaches  
International Congress on Anticancer Treatment (ICACT)  
February 2, 2010

Paris, France

442. Molecular Targeted Therapy for Advanced Renal Cell Carcinoma  
International Congress on Anticancer Treatment (ICACT)  
February 3, 2010  
Paris, France
443. Novel Approaches to Advanced Castration Resistant Prostate Cancer  
International Congress on Anticancer Treatment (ICACT)  
Presidential Symposium  
February 3, 2010  
Paris, France
444. New Treatment Modalities for Prostate Cancer - What Have We Learned and  
What are The Opportunities?  
Interactive Genitourinary Cancer Conference (IGUCC)  
February 25, 2010  
Athens, Greece
445. Exploring Unmet Needs in mCRPC – What Does the Future Hold?  
3rd World Congress on Controversies in Urology (CURy)  
February 27, 2010  
Athens, Greece
446. Management of Patients with Advanced with Prostate Cancer  
La Sapienza University  
April 15, 2010  
Rome, Italy
447. The Potential of Denosumab across the Prostate Cancer Continuum of Care  
Congress of the European Association of Urology (EAU)  
April 18, 2010  
Barcelona, Spain
448. Medical Uro-Oncology - ESU Course 36  
Chairman  
European School of Urology  
Congress of the European Association of Urology (EAU)  
April 19, 2010

Barcelona, Spain

449. Small Molecules as Novel Anticancer Agents: “Smart Drugs”?  
ESU Course 36  
European School of Urology  
Congress of the European Association of Urology (EAU)  
April 19, 2010  
Barcelona, Spain
450. Application of Chemotherapeutic Agents in Bladder Cancer  
Course Chairman  
European School of Urology  
Congress of the European Association of Urology (EAU)  
April 19, 2010  
Barcelona, Spain
451. Current and Emerging Treatment Options for Patients with Advanced Prostate Cancer  
Congress of the European Association of Urology (EAU)  
April 19, 2010  
Barcelona, Spain
452. Clinical Research and Systemic Treatment in Castration Resistant Prostate Cancer  
Visiting Professor  
Department of Urology  
RWTH Aachen University  
April 28, 2010  
Aachen, Germany
453. Modern Treatment in Metastatic Renal Cell Cancer  
Visiting Professor  
Department of Urology  
RWTH Aachen University  
April 28, 2010  
Aachen, Germany
454. Management of Side Effects  
Congress Organizer and Moderator

Fifth European International Kidney Cancer Symposium  
May 8, 2010  
London, UK

455. Neoadjuvant and Adjuvant Chemotherapy  
Swedish Bladder Cancer Meeting  
May 20, 2010  
Malmö, Sweden

456. New Drugs in Prostate Cancer  
Regional Congress on Genito-Urinary Tumors  
Italian Association Medical Oncology (AIOM)  
May 28, 2010  
Viterbo, Italy

457. Management of Kidney Cancer  
Moderator  
Regional Congress on Genito-Urinary Tumors -  
Italian Association Medical Oncology (AIOM)  
May 28, 2010  
Viterbo, Italy

458. Is Systemic Therapy Impacting Progress in Urothelial Cancer?  
Oral Abstract Session Genitourinary Cancer  
46<sup>th</sup> Annual Meeting of the American Society of Clinical Oncology (ASCO)  
June 8, 2010  
Chicago

459. Novel Treatments in Kidney Cancer  
Challenges in Laparoscopy & Robotics 2010  
June 10, 2010  
Rome, Italy

460. What's new Behind the Corner? New Treatment Options in the Arena:  
Pazopanib  
4<sup>th</sup> Post ASCO Meeting on Advanced Kidney Cancer  
June 19, 2010  
Arezzo, Italy

461. My favorite Treatment Option: Drug Combination or Sequence  
Moderator and discussant  
4<sup>th</sup> Post ASCO Meeting on Advanced Kidney Cancer  
June 19, 2010  
Arezzo, Italy
462. High Risk Prostate Cancer – a Model for an Integrated Approach  
National Congress of the Italian Society of Oncologic Urology (SIUrO)  
June 24, 2010  
Rome, Italy
463. The Future of Renal Cell Carcioma  
RCC Renal Cancer Conference  
September 17, 2010  
Rome, Italy
464. What’s on the Horizon?  
Systemic Treatment in Bladder Cancer  
EORTC Bladder Cancer Symposium  
September 23, 2010  
Amsterdam, The Netherlands
465. Novel Targeted Agents for Kidney Cancer  
Advanced Course on Urologic Oncology: Kidney, Bladder and Prostate  
September 30, 2010  
Rome, Italy
466. Neo-adjuvant and Adjuvant Chemotherapy in Bladder Cancer  
Advanced Course on Urologic Oncology: Kidney, Bladder and Prostate  
September 30, 2010  
Rome, Italy
467. Castration Resistant Prostate Cancer  
Advanced Course on Urologic Oncology: Kidney, Bladder and Prostate  
October 1, 2010  
Rome, Italy
468. The new TKI: How Do You Integrate Pazopanib into the Treatment Paradigm of mRCC?

Satellite Symposium

35<sup>th</sup> Congress of the European Society for Medical Oncology (ESMO)

October 10, 2010

Milan

469. Phase III Trial of Pazopanib in Advanced Renal Cell Carcinoma:  
Final Overall Survival Results  
Proffered Paper session on Genitourinary Tumors  
35<sup>th</sup> Congress of the European Society for Medical Oncology (ESMO)  
October 11, 2010  
Milan
470. Abiraterone Acetate vs Placebo after Docetaxel Chemotherapy in  
Metastatic CRPC  
Presidential Symposium  
35<sup>th</sup> Congress of the European Society for Medical Oncology (ESMO)  
October 11, 2010  
Milan
471. Novel Targeted Agents in the Treatment of Advanced Kidney Cancer  
Annual Meeting of the Japan Society of Clinical Oncology (JSCO)  
October 29, 2010  
Kyoto, Japan
472. Inhibition of Angiogenesis in the Management of RCC: What's the Current  
Status?  
Breast and Renal Cell Carcinomas: Improving Outcomes by Targeting Shared  
Signalling Pathways  
Annual Meeting of the Japan Society of Clinical Oncology (JSCO)  
October 29, 2010  
Kyoto, Japan
473. Novel Therapies in the Treatment of Castration Resistant Prostate Cancer  
ASCO-JSCO Joint Symposium  
Annual Meeting of the Japan Society of Clinical Oncology (JSCO)  
October 30, 2010  
Kyoto, Japan
474. RCC: Beyond First Line Treatment: Considerations and Perspectives

AIOM ( Italian Society of Medical Oncology)  
November 5, 2010  
Rome, Italy

475. Tumori dell'Apparato Uro-Genitale: What's new?  
Education Session  
AIOM ( Italian Society of Medical Oncology)  
November 7, 2010  
Rome, Italy

476. Medical Advances in Renal Cancer  
National Cancer Research Institute Cancer Conference  
November 10, 2010  
Liverpool, England

477. Recent Addings to the Armamentarium in the First Line Setting: Pazopanib and  
Advanced Clear Cell Cancer  
SOGUG ( Spanish Oncologic Genitourinary Group) Scientific Meeting  
November 20, 2010  
Madrid, Spain

478. Chemotherapy and Targeted Therapies. News in Bladder and Prostate Tumors.  
Meet the Professor  
November 30, 2010  
Vienna, Austria

479. Bladder Cancer 2010  
Grandangolo 2010  
December 16, 2010  
Genoa, Italy

480. Renal Cell Carcinoma: A Glance to Future  
Expert Dialogues: Optimizing Renal Cell Carcinoma Treatment  
January 28, 2011  
Paris, France

481. Treatment of High-risk Patients with Advanced Prostate Cancer Using a Multi-disciplinary Approach  
Satellite Symposium. A Multidisciplinary Treatment Team Approach to Metastatic Hormone-Refractory Prostate Cancer  
4th World Congress on Controversies in Urology (CURy)  
January 28, 2011  
Paris, France
482. Selecting Targeted Agents for the Treatment of Advanced RCC  
Urologists, RCC & Targeted Agents: Applying Clinical Evidence to Clinical Practice  
4th World Congress on Controversies in Urology (CURy)  
January 29, 2011  
Paris, France
483. Novel Therapeutics in RCC  
Genito-Urinary Session 1  
22<sup>nd</sup> International Congress on Anticancer Treatment (ICACT)  
February 1, 2011  
Paris, France
484. Castration Resistant Prostate Cancer – Where Are We Now?  
Genito-Urinary Session 2  
22<sup>nd</sup> International Congress on Anticancer Treatment (ICACT)  
February 3, 2011  
Paris, France
485. Castration Resistant Prostate Cancer – Where Are We Now?  
Presidential Session  
22<sup>nd</sup> International Congress on Anticancer Treatment (ICACT)  
February 3, 2011  
Paris, France
486. Medical Therapy in Renal Cancer  
4<sup>th</sup> National Course on Geriatric Oncology  
Highlights in Cancer Treatment of the Elderly  
February 8, 2011  
Rome



487. Promising New Agents in Development for Advanced GU  
SAGE Genitourinary Cancers Meeting  
February 16, 2011  
Orlando, USA
488. Association of Genetic Markers in Angiogenesis- or Exposure-related Genes with Overall Survival in Pazopanib (P) Treated Patients (Pts) with Advanced Renal Cell Carcinoma  
Oral Abstract Session on Renal Cancer  
The Genitourinary Cancers Symposium  
February 19, 2011  
Orlando, USA
489. Educational Overview: New Targets and Drugs in Prostate Cancer Plenary Session 1. Targeting the androgen axis in prostate cancer.  
International Symposium on Targeted Anticancer Therapies  
March 8, 2011  
Paris, France
490. Another Anti-VEGF?  
Round Table Discussion on Treatment of Relapse after Failure of First-line Anti-VEGF Therapy.  
5<sup>th</sup> Postgraduate Seminar on Urological Cancer  
March 11, 2011  
Athens, Greece
491. State of the Art Treatment in 1<sup>st</sup> Line RCC  
Scientific Symposium  
5<sup>th</sup> Postgraduate Seminar on Urological Cancer  
March 12, 2011  
Athens, Greece
492. Chapter 9 : Metastatic Disease  
ICUD-EAU International Consultation on Bladder Cancer  
26<sup>th</sup> Annual Congress of the European Association of Urology (EAU)  
March 18, 2011  
Vienna, Austria

493. Emerging Targeted Therapies for Advanced Prostate Cancer  
Scientific Symposium  
26<sup>th</sup> Annual Congress of the European Association of Urology (EAU)  
March 19, 2011  
Vienna, Austria
494. Application of Novel Hormonal Strategies in Prostate Cancer  
ESU Course 36  
26<sup>th</sup> Annual Congress of the European Association of Urology (EAU)  
March 21, 2011  
Vienna, Austria
495. Small Molecules as Novel Anticancer Agents “Smart Drugs” in Renal Cancer  
ESU Course 36  
26<sup>th</sup> Annual Congress of the European Association of Urology (EAU)  
March 21, 2011  
Vienna, Austria
496. Androgen Biosynthesis Inhibitors: Clinical Data and Practical Management in  
Castrate-Resistant Prostate Cancer  
Scientific Symposium  
26<sup>th</sup> Annual Congress of the European Association of Urology (EAU)  
March 21, 2011  
Vienna, Austria
497. Role of Circulating Tumor Cells in Predicting Survival in Men with Castration  
Resistant Disease  
Models to Predict Prognosis in Advanced Disease  
MSKCC/ESO 2nd Interdisciplinary Conference  
Prostate Cancer: Predictive Models for Decision Making  
April 8, 2011  
New York, USA
498. New Treatment Options. What’s New Around the Corner?  
13<sup>th</sup> Course on Advances in Urological Oncology  
Focus on Renal Cancer  
April 30, 2011  
Erice, Italy

499. Picking the Optimal Treatment for Patients with Metastatic Hormone Refractory Prostate Cancer  
Meet the Professor Seminar  
European Institute of Oncology  
May 4, 2011  
Milan, Italy
500. New TKIs  
New Agents in Renal Cell Carcinoma  
Sixth European International Kidney Cancer Symposium  
May 6, 2011  
Warsaw, Poland
501. Clinical Application of Treatment Guidelines: Newly Diagnosed Advanced RCC  
Navigating through the Advanced RCC Treatment Landscape: An Evidence-Based Treatment Approach  
Sixth European International Kidney Cancer Symposium  
May 6, 2011  
Warsaw, Poland
502. New Treatment Options in Prostate Cancer. What's New Around the Corner?  
2nd Interdisciplinary Conference "Prostate Cancer": Predictive Models for Decision Making.  
National Congress of the Italian Society of Oncologic Urology (SIUrO)  
June 22, 2011  
Naples, Italy
503. New Treatments for Cancer  
Moderator  
Sixth Annual Scientific Conference of the Istituto Toscano Tumori (ITT)  
July 1, 2011  
Carmignano, Italy
504. Current Questions in Clinical Research for Prostate Cancer  
Brainstorming Conference about the Research in Prostate Cancer  
September 17, 2011  
Bellinzona, Switzerland
505. Androgen Biosynthesis Inhibitors: Clinical Data and Patient Management

Evolving Treatment Options in Castration-resistant Prostate Cancer  
16th ECCO – 36th ESMO Multidisciplinary Cancer Congress  
September 23, 2011  
Stockholm, Sweden

506. Novel Treatments for Castration-resistant Prostate Cancer  
Educational Symposium on Medical Treatment of Metastatic Prostate Cancer  
16th ECCO – 36th ESMO Multidisciplinary Cancer Congress  
September 26, 2011  
Stockholm, Sweden
507. More Than Just Hormones: Highways and Byways in Castration-resistant Prostate Cancer  
Junctions, Flyovers and Crossroads: Mapping the Intersections in Targeted Cancer Therapy  
16th ECCO – 36th ESMO Multidisciplinary Cancer Congress  
September 26, 2011  
Stockholm, Sweden
508. The Combination of Multi-modality Treatment is the Best Approach for the Treatment of High-risk Prostate Cancer  
Oxford Union Style Debate  
16th ECCO – 36th ESMO Multidisciplinary Cancer Congress  
September 26, 2011  
Stockholm, Sweden
509. State of the Art and Future in the Treatment of Renal Cancer  
Therapeutic Integration in Metastatic Renal Cell Carcinoma  
Update in Renal Cancer: What's New in 2011  
October 6, 2011  
Rome, Italy
510. State-of-the-art Lecture: Update on Systemic Treatment in Metastasized Disease  
Session 4: Renal Cell Cancer  
The 3rd European Multidisciplinary Meeting on Urological Cancers (EMUC)  
November 4, 2011  
Barcelona, Spain
511. Overview in the Treatment of Metastatic Renal Cell Carcinoma

Symposium on Metastatic Renal Cell Carcinoma: Scientific Evidence and Clinical Practice  
XIIIth National Congress of the Italian Association of Medical Oncology (AIOM)  
November 5, 2011  
Bologna, Italy

512. Therapeutic Algorithm in Advanced Renal Carcinoma  
Third Line Therapy in Renal Cell Carcinoma  
January 18, 2012  
Rome, Italy

513. Current Status of Neo-adjuvant and Adjuvant Chemotherapy in Muscle Invasive Bladder Cancer  
Joint ESOU, EORTC, ESUR, Pathology Session.  
27th Annual Congress of the European Association of Urology (EAU)  
March 25, 2012  
Paris, France

514. Advanced Urothelial Carcinoma  
Co-Chair Poster Session 72  
27th Annual Congress of the European Association of Urology (EAU)  
March 27, 2012  
Paris, France

515. Back to the Future with Hormonal Therapy for CRPC  
Co-Chair Satellite Symposium  
27th Annual Congress of the European Association of Urology (EAU)  
March 27, 2012  
Paris, France

516. What are Upcoming Agents, Concepts and Ideas?  
Systemic Treatment in Kidney Cancer at a Glance  
Expanding Circles in Supporting Kidney Cancer  
March 12, 2012  
Rome, Italy

517. Targeted Therapies and the Long-term Treatment of mRCC  
European Kidney Cancer – Patient Advocates Advisory Board

March 14, 2012  
Brussels, Belgium

518. New Drugs for Patients with CRPC  
Session: Medical Management of Uro-Oncology Should be Managed by Urologists  
5th EAU Leading Lights in Urology  
March 29, 2012  
Madrid, Spain
519. Second-line Therapy after Initial TKI Failure: Weighing the Evidence  
3rd Annual Conference of renal cancer Experts (CORE)  
April 20, 2012  
Munich, Germany
520. Science Session Chairman  
European Kidney Cancer Association Symposium  
May 4, 2012  
Vienna, Austria
521. Which Treatment after Docetaxel for Hormone-Resistant Prostate Cancer?  
2nd International Conference “Translational Research in Oncology: A New Approach to Personalized Medicine”  
May 10, 2012  
Forlì, Italy
522. Novel Therapies for the Treatment of Castration Resistant Prostate Cancer  
State of the Art Lecture  
Cancer Grand Rounds  
Comprehensive Cancer Center in Vienna  
May 16, 2012  
Vienna, Austria
523. Renal Cell Carcinoma Biology and Targeted Therapies  
European Network for Cancer Research in Children  
Workshop on Renal Tumors Biology Driven Drug development  
Policlinico Univeritario “A. Gemelli”  
June 9, 2012  
Rome, Italy

524. Chemotherapy: Why Neoadjuvant?  
Multidisciplinary Discussion: Locally Advanced and Metastatic Bladder Cancer  
XXII Annual Meeting of the Italian Society of Oncologic Urology (SIUrO)  
June 13, 2012  
Bologna, Italy
525. Delivering High-Quality Cancer Care in an Age of Austerity  
ESO Panel Discussion  
Can Europe Cope with the Rising Burden of Cancer?  
Event Organized by the Italian Ministry of Health  
June 19, 2012  
Rome, Italy
526. Recent Advances in Hormone Relapsed Prostate Cancer  
The British Association of Urological Surgeons (BAUS) Annual Meeting  
June 27, 2012  
Glasgow, UK
527. Bladder Cancer Case Conference. Panel Discussion  
The British Association of Urological Surgeons (BAUS) Annual Meeting  
June 27, 2012  
Glasgow, UK
528. Primary, Secondary, and Quality-of-life Endpoint Results from the Phase 3  
AFFIRM Study of MDV3100, an Androgen Receptor Signalling Inhibitor  
Poster & Video Award Session  
Global Congress on Prostate Cancer  
June 30, 2012  
Brussels, Belgium
529. Recent Advances in the Treatment of Castration Resistant Prostate Cancer  
Columbia University  
Department of Hematology/Oncology  
September 5, 2012  
New York, New York
530. Recent Advances in the Treatment of Castration Resistant Prostate Cancer  
The Treatment of Genitourinary Tumors

September 18, 2012  
Milan, Italy

531. Neoadjuvant Chemotherapy in Bladder Cancer  
European Association of Urology (EAU) /Italian Association of Urology (AURO)  
National Congress of the Italian Association of Urology (AURO)  
September 21, 2012  
Genoa, Italy
532. Recent Advances in Hormone Relapsed Prostate Cancer  
National Congress of the Italian Association of Urology (AURO)  
September 21, 2012  
Genoa, Italy
533. Novel Hormonal Therapy for Castration-Resistant Prostate Cancer  
The Current Management of Castrate-Resistant Prostate Cancer (CRPC)  
Educational Session  
European Society of Medical Oncology Annual Meeting (ESMO)  
September 29, 2012  
Vienna, Austria
534. Rationale and Results of the AFFIRM and PREVAIL Studies of Enzalutamide (MDV3100) an Androgen Receptor Signaling Inhibitor  
Meet the Expert Session  
European Society of Medical Oncology Annual Meeting (ESMO)  
September 30, 2012  
Vienna, Austria
535. Addressing Unmet Needs in Metastatic Castration Resistant Prostate Cancer  
Cabozantinib (XL184) Prostate Cancer Clinical Trial Recruitment Symposium  
European Society of Medical Oncology Annual Meeting (ESMO)  
September 30, 2012  
Vienna, Austria
536. Results of the COMPARZ Trial in Patients with Metastatic Renal Cell Carcinoma  
Around the Patient: Pazopanib and Lapatinib in Oncology  
October 12, 2012  
Verona, Italy



537. Targeted Therapies: State of the Art and Future Perspectives  
Partial Nephrectomy and New Technology  
October 19, 2012  
Rome, Italy
538. What are the New Developments in mRCC?  
Expert Dialogues: Optimising Treatment of Metastatic Renal Cell Carcinoma  
October 26, 2012  
London, UK
539. Lost in Translational Medicine: Biomarkers  
Expert Dialogues: Optimising Treatment of Metastatic Renal Cell Carcinoma  
October 27, 2012  
London, UK
540. Primary, Secondary, and Quality-Of-Life Endpoint Results from the Phase 3  
Affirm Study of Enzalutamide (MDV3100), an Androgen Receptor Signaling  
Inhibitor  
Genitourinary Tumors Session  
Annual Meeting of the Italian Association of Medical Oncology (AIOM)  
October 28, 2012  
Rome, Italy
541. Future Outlook for Patients with mRCC  
Annual Meeting of the Italian Association of Medical Oncology (AIOM)  
October 29, 2012  
Rome, Italy
542. Medical Oncologist: Medical Treatment in the Non-Metastatic CRPC Setting,  
Where Do We Stand?  
Multimodality Treatment of Early CRPC  
Embracing Excellence in Prostate, Bladder and Kidney Cancer (EMUC)  
4<sup>th</sup> European Multidisciplinary Meeting on Urological Cancers  
November 16, 2012  
Barcelona, Spain
543. Management of Renal Cell Carcinoma  
University “La Sapienza”

November 21, 2012  
Rome, Italy

544. Hot Topics in GenitoUrinary Oncology  
Hormonal Therapy in Castration Resistant Prostate Cancer  
Milan National Cancer Institute (IST)  
November 29, 2012  
Rome, Italy
545. Management of Castration Resistant Prostate Cancer  
Tumor of the Kidney and of the Prostate  
January 17, 2013  
Rome, Italy
546. Neo-Adjuvant Chemotherapy for Muscle Invasive Bladder Cancer  
10th Meeting of the EAU Section of Oncological Urology (ESOU)  
January 20, 2013  
Rome, Italy
547. Prostate Cancer: The Clinical Trialist's Perspective  
Translations in Urologic Oncology  
January 25, 2013  
Heidelberg, Germany
548. New and Emerging Post-Chemotherapy Castration Resistant Prostate Cancer  
Treatments: Clinical experience  
European Association of Urology (EAU)  
March 16, 2013  
Milan, Italy
549. Neo.Adjuvant Chemotherapy for Muscle Invasive Bladder Cancer  
Urological Society of Australia and New Zealand (USANZ 2013)  
66<sup>th</sup> Annual Scientific Meeting  
April 14, 2013  
Melbourne, Australia
550. Second Line Anti-Androgen Therapy and Beyond for Advanced Prostate Cancer  
Urological Society of Australia and New Zealand (USANZ 2013)  
66<sup>th</sup> Annual Scientific Meeting

April 15, 2013  
Melbourne, Australia

551. Management of Castration Resistant Prostate Cancer  
Urological Society of Australia and New Zealand (USANZ 2013)  
66<sup>th</sup> Annual Scientific Meeting  
Melbourne, Australia  
April 16, 2013
552. Medical Therapy of Renal Cell Carcinoma  
Urological Society of Australia and New Zealand (USANZ 2013)  
66<sup>th</sup> Annual Scientific Meeting  
Melbourne, Australia  
April 16, 2013
553. Xp11.2 Translocation/TFE3 Fusion Renal Cell Carcinoma  
8<sup>th</sup> International Kidney Cancer Association Symposium  
May 4, 2013  
Budapest, Hungary
554. Overcoming Resistance in the Treatment of Patients with Renal and Prostate  
Cancers  
Adapting Molecular Biology in Clinical Practice  
May 10, 2013  
Rome, Italy
555. Treatment of Castration Resistant Prostate Cancer: Novel and Future Hormonal  
and Chemotherapeutic Strategies  
Innovation and Integration in Oncology: Prostate Cancer and Locally Advanced  
Non Small Cell Lung Cancer  
May 17, 2013  
Rome, Italy
556. Novel Therapies in the Management of Castration Resistant Prostate Cancer  
Treatment of Prostate and Breast Cancer: What Have We Learned and Future  
Therapies.  
May 25, 2013  
Rome, Italy

557. Novel Therapies for Prostate Cancer  
Challenges in Laparoscopy & Robotics  
10<sup>th</sup> International Congress  
June 8, 2013  
Beijing, China
558. Prevention of Lung Cancer  
Moderator  
Forlanini Hospital, Aula Magna  
June 26, 2013  
Rome, Italy
559. Design of Phase III Trial 10TASQ10  
Advisory Board on Management of Castration Resistant Prostate Cancer  
June 27, 2013  
Paris, France
560. Androgen Biosynthesis Inhibition  
Prostate Cancer Therapeutic Area Steering Committee Meeting  
June 28, 2013  
Amsterdam, The Netherlands
561. Micro RNA and Cancer  
Moderator  
Eighth Annual Scientific Conference Institut of Oncology Tuscany  
July 5, 2013  
Cortona, Italy
562. Opening Session: Biological Basis of Personalised Cancer Therapy  
Panel Member  
European Society of Medical Oncology Annual Meeting (ESMO)  
September 28, 2013
563. Keynote Lecture: The Mouse Hospital and the Co-Clinical Trial Project  
Chair  
European Society of Medical Oncology Annual Meeting (ESMO)  
September 28, 2013  
Amsterdam, The Netherlands

564. Scientific Symposium: New Challenges in mRCC: Identifying What is Worth Pursuing.  
Co-Chair  
European Society of Medical Oncology Annual Meeting (ESMO)  
September 29, 2013
565. Presidential Session III: Best and Later Breaking Abstracts  
Cora Chair  
European Society of Medical Oncology Annual Meeting (ESMO)  
September 30, 2013  
Amsterdam, The Netherlands
566. Educational Symposium: Optimal Approach for Renal Cancer  
Cora Chair  
European Society of Medical Oncology Annual Meeting (ESMO)  
September 30, 2013  
Amsterdam, The Netherlands
567. Special Lecture Can Drug Approval Keep Pace With Translational Research in Cancer?  
Chair  
European Society of Medical Oncology Annual Meeting (ESMO)  
September 30, 2013  
Amsterdam, The Netherlands
568. Genitourinary Malignancies – Other  
Teaching Lecture: Modern Management of Penile Cancer  
European Society of Medical Oncology Annual Meeting (ESMO)  
September 30, 2013  
Amsterdam, The Netherlands
569. Genitourinary Malignancies – Prostate  
Special Session: Castration Resistant Prostate Cancer: New Therapies  
European Society of Medical Oncology Annual Meeting (ESMO)  
September 30, 2013  
Amsterdam, The Netherlands
570. Renal Cell Carcinoma

Therapeutic Integration with Target Treatments in Oncology. Medical School of  
Oncology

October 5, 2013

Rome, Italy

571. Metastatic Castration Resistant Prostate Cancer. Hot Topics: Treatment  
Evaluation and Sequencing.

Panel Member

National Congress of the Italian Society of Medical Oncology (AIOM)

October 11, 2013

Milan, Italy

572. Genitourinary Tumors. Educational Session.

Moderator

National Congress of the Italian Society of Medical Oncology (AIOM)

October 11, 2013

Milan, Italy

573. Further Hormone Therapies in Abiraterone and Enzalutamide.

ESMO Preceptorship Programme - Prostate Cancer

Multidisciplinary Management, Standards of Care, Therapeutic Targets and  
Future Perspectives.

October 16, 2013

Berlin, Germany

574. Role of Standard Cytotoxic Chemotherapy, First and Second-Line.

ESMO Preceptorship Programme - Prostate Cancer

Multidisciplinary Management, Standards of Care, Therapeutic Targets and  
Future Perspectives.

October 17, 2013

Berlin, Germany

575. Management of mRCC: What Have We Achieved?

Expert Dialogues 2013: Optimising Clinical Practice for Improved Patient  
Outcomes.

November 8, 2013

Paris, France

576. Personalized Medicine: Can It be Achieved in mRCC?

- Co-Chair  
Expert Dialogues 2013: Optimising Clinical Practice for Improved Patient Outcomes.  
November 9, 2013  
Paris, France
577. Setting the Scene - Keynote Lecture in Prostate, Kidney and Bladder Cancer.  
Co-Chair  
5<sup>th</sup> European Multidisciplinary Meeting on Urological Cancers  
November 15, 2013  
Marseille, France
578. Targeting Androgen Signaling Beyond Castration Resistance  
Rapidly Evolving Options in the Management of Castration Resistant Prostate Cancer: Practical Guidance for Clinicians  
5<sup>th</sup> European Multidisciplinary Meeting on Urological Cancers  
November 16, 2013  
Marseille, France
579. New Targets in the Treatment of Prostate Cancer  
Personalization and Strategy in the Treatment of Prostate Cancer. National Meeting of the Italian Society of Medical Oncology (AIOM)  
November 23, 2013  
Naples, Italy
560. Further Hormonal Therapies Including Abiraterone and Enzalutamide  
ESMO Preceptorship Programme - Prostate Cancer  
November 28, 2013  
Lugano, Switzerland
561. Alternative and Second Line Chemotherapy in the Management of mCRPC  
ESMO Preceptorship Programme - Prostate Cancer  
November 29, 2013  
Lugano, Switzerland
562. Inhibition of the Androgen Receptor Complex  
Treatment Options in Castration Resistant Prostate Cancer  
1. Symposium on Castration Resistant Prostate Cancer

December 7, 2013  
Düsseldorf, Germany

563. Medical Treatment in the Non-Metastatic M0 CRPC Setting:  
Where Do We Stand?  
MDV3100-14 European Investigators' Meeting: PROSPER  
January 11, 2014  
Barcelona, Spain
564. Optimal Sequence of Treatment for Metastatic Prostate Cancer  
ISCORT: The Annual Meeting of the Israeli Society for Clinical Oncology  
and Radiation Therapy  
January 14, 2014  
Eilat, Israel
565. Treatment of Advanced, Metastatic Urothelial Cancer  
ISCORT: The Annual Meeting of the Israeli Society for Clinical Oncology  
and Radiation Therapy  
January 15, 2014  
Eilat, Israel
566. Novel Therapies in Metastatic Renal Cell Cancer: Second Line  
and Beyond.  
ISCORT: The Annual Meeting of the Israeli Society for Clinical Oncology  
and Radiation Therapy  
January 17, 2014  
Eilat, Israel
567. State of the Art Treatment in mCRPC with Androgen Targeted Therapies  
Hormonal Therapies Blocking the Androgen Pathway  
The Prostate Cancer Debates 2014  
January 24, 2014  
Rome, Italy
568. Future Perspectives in Renal Cancer  
SPECIAL. CA.RE. 2014  
SPECIALists in RENal Cancer  
February 20, 2014  
Florence, Italy



569. International Workshop on New Frontiers of radiation Oncology: Re Irradiation Treatment after Failure of Hormonal Therapy in Patients with Advanced Prostate Cancer

February 28, 2014

Rome, Italy

570. Società Romana di Chirurgia

Non Colorectal Hepatic Metastasis

Tumors of Genitorunary Tract, Orientaion, and Treatment of Hepatic Metastases

La Sapienza University

Department of Surgical Science

March 5, 2014

Rome, Italy

# DARRICK T. FU

Raleigh NC 27612

(919)-802-6395

darrickfu@gmail.com

## SUMMARY

Executive with 20+ years experience in the biopharmaceutical industry, specializing in the management of complex initiatives, product development projects, and research and development alliances. Unique insight on the necessary role of all critical players in the healthcare enterprise gained through multi-sector work experience. Strong understanding of broad pharmaceutical R&D issues and innovative new trends as well as all key technical disciplines required for new product development. Expertise in integrating multiple and disparate issues into overall project strategy and building consensus/buy-in, plans, and budgets as well as managing in a changing technical, resource, or political environment. Strong communication and interpersonal skills. Areas of expertise:

- Leadership and implementation of complex strategic initiatives across multiple stakeholder interests priority constraints.
- Leadership of multi-disciplinary teams in a matrix environment across international, cross-cultural, cross-sector, and/or multi-company 'boundaries'
- Evaluation and management of projects within an uncertain environment of technical and/or resource changes
- Clinical and Preclinical and development of new products, particularly biological and vaccines which meet commercial and regulatory needs
- Evaluation of technical, clinical, regulatory, and business risks impacting projects and structuring development strategies to manage risks
- Forecasting and managing of internal and/or external resources in line with project needs
- Construction of partnerships considering the intellectual property, legal, commercial, and financial interests, as well as development goals of each party.
- Practical knowledge of challenges facing the US healthcare enterprise from medical practitioners through the innovative medical/diagnostic industry.

## PROFESSIONAL EXPERIENCE

### Pralin Management LLC, Raleigh NC

#### President & Principle Consultant

12/2010-Present

#### Projects:

- American Institute of Healthcare & Fitness: Chairman Marketing and Community Involvement committee. Provide leadership to a committee healthcare and fitness business owners to co-develop and co-market their allied independent business as a superior combined product.
- The Dermatology Center of Raleigh PA. Provide strategic consulting and implementation services in areas of Business Development, Business Operations, Electronic Medical Record, and marketing.
- Hawaii Biotechnology Inc.: consulting on development and enabling technology licensing for a recombinant dengue vaccine.

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**Duke University Medical School, Durham NC**

**3/2008-11/2010**

*Chief Product Development Officer*, Duke Human Vaccine Institute

Responsible for translating discovery research into early, proof of concept, human trials with particular emphasis on HIV/AIDS vaccine discovery. Worked through a novel consortium of academic, government, and non-profit entities that comprise the Center for HIV/AIDS Vaccine Immunology (CHAVI) and, in part, as virtual biotech organization.

Accomplishments:

- Implemented portfolio of non-human primate challenge studies to evaluate key emerging scientific concepts.
- Forged two collaborative research relationships with industry to access vaccine adjuvant technology
- Successfully prepared two inter-related NIH and Gates Foundation grants to fund a Phase I trial to validate whether in-silico antigen models are predictive of human immune response.

**Pharmaceutical Research & Manufactures Association, Washington DC**

**2/2005-3/2008**

*Associate Vice President*, Science & Regulatory Affairs

Led a major strategic initiative to help improve industrial R&D productivity across the pharmaceutical industry and speed acceptance of technical innovations and novel development tools. Developed, and implemented policy, projects, and other solutions to this problem collaboratively with industry R&D leadership, FDA leadership, NIH leadership and other stakeholders in the healthcare enterprise.

Accomplishments:

- Principle architect in establishing two major public-private-partnerships; ‘The Biomarker Consortium’ and the ‘Observational Medical Outcomes Partnership’. Established common ground across companies and with other sectors enabling progress. Responsible for the development and negotiation of all aspects required in set-up of a new entity’s operations and development of initial projects concepts.
- Successfully developed concepts for initial non-competitive biomarker projects; validation of FTG-PET as a marker for cancer outcomes and the use of Adiponectin as a marker of glycemic control as well as consensus across pharmaceutical industry, FDA, and research science (NIH).
- Developed agreement across industry on key areas of opportunity for pre-competitive effort that would improve drug development and ultimately the availability of new medicines. Organized and managed multiple technical teams to implement and pursue efforts in concert with FDA’s critical path initiative.
- Managed multiple pan-industry technical teams to develop positions and successfully advocate for regulatory change with senior FDA management.

**Development Consultant, Pinehurst NC**

**2002-2004**

Provided solutions to product development, project management, business strategy, and clinical development, in the vaccine field. Clients included Program of Appropriate Technology in Health (PATH), GlaxoSmithKline Biologicals. Highlights include:

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Rotavirus Vaccine Program LLC, PATH: Developed consensus a collaborative clinical trial program of Merck's Rotateq™ vaccine in developing countries between Merck, PATH, and other international health agencies including agreement on development strategy, study synopsis, and initial site targets.

GlaxoSmithKline Biologicals: Managed a clinical collaboration involving the US National Cancer Institute, a Costa Rican research foundation, and multiple CROs to implement a large Phase III efficacy study. Lead resolution of issues on development of clinical protocol, field procedures manuals, a data-management system, safety-reporting plan, monitoring/auditing plans, compliance with ICH/GCP and/or company SOPs, logistics plan and negotiation of agreements and budgets.

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## **GlaxoSmithKline Biologicals**

**1993-2001**

**Director**, Business Development, Rixensart Belgium

2000-2001

Supported development of strategy for new portfolio of chronic disease vaccines with objective and integrated analysis of commercial, technical, and business aspects. Valued investment opportunities in new disease areas. Responsible for managing in/out-licensing of all diagnostic related business.

### Accomplishments

- Negotiated in-licensing of 2 new research technology platforms.
- Consolidated business strategy in allergy vaccine field and corresponding I.P. position and license agreements.
- Lead negotiations for in-licensing of several chronic disease vaccines and orchestrated performance technical and I.P. due diligence and preparation of terms.
- Oversaw the termination of a major license and development agreement involving the resolution of issues from R&D, corporate legal, patent legal, and finance.

**Associate Director**, Development Alliances, Bethesda MD

1998-1999

Established and led Washington DC based staff responsible for managing US R&D collaborations with government institutions, universities, biotech companies, and contract organizations. Maximized impact/value of relationships by ensuring development of asset/product in conformity with internal and external standards. Managed an extramural development budget of ~\$10 million / year. Evaluated multiple new vaccine in-licensing opportunities to make consolidated strategic, technical and development recommendations. Recommended solutions to issues on development strategy, resource management, and portfolio priorities as a member of the senior management development committee.

### Accomplishments

- Lead SBB/Medimmune alliance on HPV vaccine to integrate strategic and overall planning and coordination between parties which resulted in initiation of Phase IIb feasibility studies within 2 years.
- Directed 3 extra-mural projects to accomplish preclinical-and Phase I development completely through contractors and collaborators. Negotiated agreements, budgets and managed collaborators.

**Assistant Director**, R&D Project Management, Rixensart Belgium

1996-1998

Created company-wide process for vaccine development which consolidated best practices and philosophies/strategies for new product development. Outlined generic network of activities and decision points, provided tools to enable improved planning, monitoring and management, and clarified roles and

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responsibilities of players. Trained, developed, and managed 2 new project managers to provide development expertise and direction to project teams.

## Accomplishments

- Developed a Vaccine Development handbook to provide functional guidance to project managers and team members. Served as reference source for training/coaching new managers.
- Directed extra-mural research program on Dengue vaccines which led to selection an in-licensing of a lead candidate.

**Senior Project Manager**, R&D Project Management , Rixensart Belgium

1993-1996

Managed 6 vaccine projects, including Lyme, Improved Flu, HIV, therapeutic-HBV, therapeutic-HPV, and cancer. Coordinated multi-disciplinary teams of 20+ people. Integrated marketing, technical, regulatory, and patent/legal issues into development strategy, preparation and implementation of plans, monitoring activities and progress, resolving issues, and reporting to senior management.

## Accomplishments

- Lead Lymerix™ Project Team from first administration to man through PLA submission to accomplished the development and licensure of a new recombinant biological within record time, beating a major competitor to market.
- Directed preclinical development teams to accomplish the submission of over 10 INDs/CTXs for new biologics.
- Led improved Flu project team to evaluate four candidate vaccines and reach key Go/No Go development decision points within two years.

**SmithKline Beecham Pharmaceuticals**

**1989-1993**

4 years additional project management experience in development of small molecules and biologics at all stages including Rx-OTC switch, across several therapeutic areas. Details and accomplishments available upon request.

## EDUCATION

**MBA**, Finance, George Washington University, 1988

**BS**, Biochemistry/Molecular Biology, Carnegie-Mellon University, 1984

**MS**, Pharmaceutical Science, (Degree not completed),

University Libre de Bruxelles, 1995 - 1996

## PUBLICATIONS

CA Altar, D Amakye, D Bounos, J Bloom, G Clack, R Dean, V Devanarayan, **D Fu**, S Furlong, L Hinman, C Girman, C Lathia, L Lesko, S Madani, J Mayne, J Meyer, D Raunig, P Sager, SA Williams, P Wong and K Zerba. A Prototypical Process for Creating Evidentiary Standards for Biomarkers and Diagnostics. Clinical Pharmacology & Therapeutics, Vol. 83, N.2: p.368-371 Feb 2008.

A.Chatterjee, P Corr, J. Evelhoch, **D. Fu**, R. Hargreaves, C. Jaffe, M. Klimas, G. Schmitz, L. Schwartz, 2005 IBM Imaging Biomarker Summit: Engaging the Discussion on the Use of Imaging Biomarkers in Pharma R&D, Medical Research, and Clinical Care. Health Industry Insights, June 2008

C. Van Hoecke, **D. Fu**, D. De Grave, P. Voet, E. Lebacqz. Clinical and immunological assessment of a candidate Lyme disease vaccine in healthy adults: Effect of a booster dose at month 12. Vaccine, 16(17): p1688-1692, 1998

F. Meurice, D. Parenti, **D. Fu**, and D.S. Krause. Specific Issues in the Design and Implementation of an Efficacy Trial for a Lyme Disease Vaccine. Clinical Infectious Diseases, 1997; 25(suppl 1):s71-75.

C. Van Hoecke, M. Comberbach, D. De Grave, P.Desmons, **D.Fu**, P.Hauser, E. Lebacqz, Y. Lobet, and P.Voet. Evaluation of the safety, reactogenicity and immunogenicity of three recombinant outer surface protein (OspA) lyme vaccines in healthy adults. Vaccine, 14(17-18): p1620-1626, 1996

### **INVITED PRESENTATIONS**

“The Biomarker Consortium: A New Paradigm to Advance Medical Science”, IBC 5<sup>th</sup> Annual Targeting Metabolic Syndrome Conference, Feb 26-28, 2007, Boston MA.

“Collaborative Efforts under the Critical Path Initiative”, Challenges and Practical Aspects of Assessing Clinical QT Prolongation / Proarrhythmia and Implications for the Critical Pathway, DIA workshop, May 8-9, 2006, Washington DC.

“Public Private Partnerships for Biomarkers”, American Institute for Medical & Biological Engineering, 15<sup>th</sup> Annual Event, March 2 2006, National Academy of Sciences, Washington DC.

“FDA-NIH-PhRMA Biomarker Consortium”, International Conference on Drug Development, February 14 2006, Austin TX.

**Curriculum Vitae**  
**David Edward Weng, M.D., Ph.D.**  
-March 2014-

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(410) 573-5305 (Main Fax)  
[dweng@aahs.org](mailto:dweng@aahs.org)  
[www.aahs.org](http://www.aahs.org)

***Permanent Address:*** 9017 Spring Hill Ln  
Chevy Chase, MD 20815  
(301) 652-7370 (home)  
[davidweng7@gmail.com](mailto:davidweng7@gmail.com)

***Personal:*** Born June 25, 1962 in Chicago, Illinois  
Married with 5 children  
U.S. Citizen

***Professional Summary:***

Dr. David E. Weng is a medical oncologist with Anne Arundel Medical Center, joining the medical staff in March, 2014. In addition to clinical responsibilities for the care of patients with hematologic and solid tumor malignancies, he is also involved with clinical trials, health care outcomes and quality management research.

He was previously the chief medical officer and senior vice president for TetraLogic Pharmaceuticals in Malvern, PA. At TetraLogic, Dr. Weng advanced the clinical development of birinapant, (novel small molecule in the class of Smac mimetic agents) from preclinical studies to phase 2 clinical studies for both solid and hematologic malignancies. In addition, he was primarily responsible for the development of external preclinical and clinical collaborations, and the building of company capabilities in clinical development, operations, regulatory affairs, and data management. At TetraLogic, he oversaw pharmacovigilance, and management of interactions with contract research organizations, key academic institutions and opinion leaders, in the US, Asia, and Europe. Dr. Weng contributed to strategic planning, corporate development, business development, translational studies, preclinical research, and communication with investors.

Dr. Weng joined the biotechnology industry as Director of Clinical Oncology Development at MedImmune, LLC in Gaithersburg, MD from 2006-09, in order to pursue career opportunities in drug development and business development for new health care approaches. During this time,

he oversaw clinical development in multiple areas of unmet need, requiring a breadth of knowledge of hematology and oncology, and ongoing discussion with key opinion leaders about current and emerging therapies for unmet needs. As part of MedImmune and the parent company AstraZeneca, he led multiple product development teams and collaborations with academic and industry partners for phase 1 clinical studies for both small molecules and biologics.

Before joining the biotechnology industry, Dr. Weng was a faculty member of the Department of Hematology and Medical Oncology and the Taussig Cancer Center at the Cleveland Clinic Foundation from 1998-2006. While at the Clinic, he was a clinical oncologist, seeing patients of all diagnoses and disease stages, with particular expertise in breast cancer. In addition, he contributed to institutional capabilities as director for the Hematology/Medical Oncology Fellowship Program, overseeing the recruitment and training of fellows to careers for both academic and community practice. Dr. Weng was also vice chairman of the Cleveland Clinic Institutional Review Board, overseeing review of new and ongoing programs of clinical research. He has been an advisor and investigator for development of new approaches including target selection, preclinical drug development, chemotherapy cytotoxic agents, hormonal therapies, small molecule agents, monoclonal antibodies, cellular therapies, diagnostics, and imaging. As an academic investigator, Dr. Weng has been involved with multiple biotechnology companies including Ribozyme Pharmaceuticals (now SIRNA), Immunicon (now Veridex), American Bioscience, Inc (now Abraxis Bioscience), Advanced BioPhotonics, Inc., and Genomic Health, Inc. Dr. Weng has been a key opinion leader member of advisory panels and speaker bureaus for Genentech, Sanofi-Aventis, AstraZeneca, Abraxis Biosciences, and Genomic Health Inc.

Dr. Weng has been involved as an investigator in over 30 oncology studies during his research career. Dr. Weng has over 60 peer-reviewed publications and abstracts in the fields of developmental biology, cancer biology, immunology, and clinical research.

Dr. Weng is board-certified by the ABIM in medical oncology and has expertise and clinical experience in the care of hematology and oncology patients. He earned his bachelor's degree in biochemical sciences from Harvard University and medical and doctorate degrees from the Johns Hopkins University School of Medicine. He completed his internal medicine residency training at the Johns Hopkins Hospital, followed by fellowship training in medical oncology at the National Cancer Institute. He continues to maintain active licenses for Federal DEA prescription privileges for controlled substances and state medical licensure in Maryland, Ohio, and California.

***Personal Summary:***

Dr. Weng was born in Chicago, IL and grew up in Rochester, MI with his parents and 2 younger brothers. He lives in Chevy Chase, MD with his wife and 5 children. When not occupied with family or work, he is an avid runner, looking for any chance to run trails in local parks.



***Education:***

- (1980-1984) A.B. - Biochemical Sciences, Harvard University, Cambridge, MA.
- (1984-1992) M.D. - Johns Hopkins Univ. School of Medicine, Baltimore, MD
- (1986-1992) Ph.D., Biochemistry, Cellular and Molecular Biology, -Johns Hopkins Univ. School of Medicine, Baltimore, MD
- (1992-1995) Internal Medicine Internship and Residency, Johns Hopkins Hospital, Department of Medicine, Baltimore, MD
- (1995-1998) Medical Oncology Fellowship -National Cancer Institute, Bethesda, MD

***Professional Experience:***

- (2014-present) –Attending Physician of Medical Staff, Anne Arundel Medical Center
- (2012-14) – Senior Vice President, TetraLogic Pharmaceuticals, Malvern, PA
- (2010-14) – Chief Medical Officer, TetraLogic Pharmaceuticals, Malvern, PA
- (2009-10) – Vice President, Clin Onc, TetraLogic Pharmaceuticals, Malvern, PA
- (2006-09) – Director, Clinical Development, MedImmune, LLC, Gaithersburg, MD
- (2005-06) - Acting Director, Breast Medical Genetics Clinic, Cleveland Clinic Foundation, Cleveland, OH
- (2004-06)- Director, Hematology and Medical Oncology Fellowship Program, Cleveland Clinic Foundation, Cleveland, OH.
- (1998-2006) - Staff, Department of Hematology and Medical Oncology, Cleveland Clinic Foundation, Cleveland OH.
- (2001-06) - Institutional Biosafety Committee, Cleveland Clinic Foundation. Cleveland, OH
- (2000-06) Institutional Review Board, Vice-Chairman, Cleveland Clinic Foundation, Cleveland OH.
- (2000-2006) - Board of Trustees, Northern Ohio Breast Cancer Coalition, Brecksville, OH
- (1997-98) - Clinic Attending, Breast Cancer Section, Medicine Branch, Division of Clinical Sciences, National Cancer Institute. Bethesda, MD.
- (1997-98) - Protocol Study Chairman, Department of Experimental Transplantation and Immunology, Medicine Branch, Division of Clinical Sciences, National Cancer Institute. Bethesda, MD
- (1996-98) - Kaiser Permanente Health Care Urgent Care Center, Kensington, Maryland
- (1995-98) - U.S. Public Health Service Commissioned Corps, National Institutes of Health, Bethesda, MD
- (1996-98) - Postdoctoral Research - Dendritic Cell Biology and Tumor-mediated Immunosuppression, in the lab of Peter Cohen, M.D., National Cancer Institute. Bethesda, MD
- (1995-98) - Medical Oncology Fellowship Medicine Branch, National Cancer Institute, Bethesda MD.
- (1992-95) - Internal Medicine Residency -The Osler Medicine Service, Department of Medicine, Johns Hopkins Hospital. Baltimore,MD
- (1984-92) - Ph.D. Thesis, "Analysis of Gene Expression During Mouse Early Development" in the lab of John D. Gearhart, Ph.D., Dept. of Physiology, Johns Hopkins University School of Medicine. Baltimore, MD.
- (1984) -Enzyme kinetics and steroid biochemistry research in the lab of Paul Talalay, M.D., Dept. of Pharmacology, Johns Hopkins University School of Medicine. Baltimore, MD
- (1982-84) - Drosophila molecular genetics research in the lab of Welcome Bender, Ph.D.,

***Pharmaceutical Industry Research Experience and Team Accomplishments***

***TetraLogic Pharmaceuticals (7/2009-2/2014)***

1. **TL32711 – SMAC Mimetic** (Clinical Development Leader): Clinical leader to develop a novel targeted anti-cancer therapeutic, with cross-functional team activities to submit the FDA IND application to initiate first-in-human clinical studies. Additional activities include development of preclinical research activities to support the clinical development plan, development and implementation of biomarker strategies for clinical use, business development for venture capital investment and corporate partnering, development and implementation of clinical plans for successful regulatory approval and commercial outcomes.

***MedImmune Oncology (9/2006 – 7/2009)***

1. **MEDI-561 - Hsp90 inhibitor** (Project Development Team Leader): Team leader since inception of Hsp90 inhibitor program at MedImmune in Sep06, with management of MedImmune program development and collaboration/coordination with Infinity Pharmaceuticals across all functional areas of project development. Our PDT activities have led to a number of accomplishments, currently supporting our primary goals to develop successful registration efforts. Accomplishments include FDA IND approval in Nov 07, orphan drug designation approval in the US and EU, conduct of multiple Phase 1 and Phase 2 trials, first round SPA approval of a multinational Phase 3 registration effort.
2. **MEDI-538 – CD19 BiTE** (Project Development Team Leader): Started as team member in Sep06. Led team effort to respond to FDA Clinical Hold of Sep06 of initial IND submission of Aug06, leading to FDA IND approval in Feb07. Led MedImmune PDT efforts in collaboration with co-development partner Micromet PDT. Assumed team leadership role to develop clinical development plans for PDC review in Feb07. Led team efforts to identify alternate formulations for MEDI-538 delivery. Transitioned my responsibilities to another member of MedImmune Oncology in May07 to devote greater efforts to MEDI-561 activities.
3. **MEDI-531 – EphA2 monoclonal antibody** (Project Development Team Leader): Onset of team member activities in Sep06, with involvement in evaluation of animal toxicology results that led to subsequent recommendation for program discontinuation.
4. **MEDI-543 – EphA2 listeria vaccine** (Project Development Team member): Onset of team member activities in Dec06, with involvement in evaluation of nonclinical efficacy and current outside clinical activities of co-development partner. Subsequent efforts led to recommendation for program discontinuation.
5. **MEDI-547 – EphA2 monoclonal-drug conjugate** (Project Development Team Leader): Onset of team activities in Jun07, with involvement in evaluation of non-clinical data, selection of clinical candidate, development of IND enabling activities, and primary responsibility for formulating clinical development plans.

Accomplishments include FDA IND acceptance in Dec 08, Phase 1 clinical implementation in Aug 09, orphan drug designation in ovarian cancer in the US and EU, NCI selection of MEDI-547 as a program for CTEP co-development.

6. **MEDI-565 – CEA BiTE** (Project Development Team Leader): Onset of team activities in Oct06, with involvement in evaluation of nonclinical data, selection of clinical candidate, development of IND enabling activities and primary responsibility for formulating clinical development plans. Accomplishments include FDA agreement of the proposed Phase 1 trial design in pre-IND Type B meetings.
7. **MEDI-EphA2 BiTE – EphA2 BiTE** (Project Development Team member): Onset of team member activities in Oct06, with involvement in evaluation of nonclinical data, selection of clinical candidate, and formulating the clinical development plans.
8. **MEDI-3617 –Ang2 monoclonal antibody** (Product Development Team member) Onset of team activities in Oct08, with involvement in evaluation of nonclinical data,, development of IND enabling activities and primary responsibility for formulating clinical development plans.
9. **Business Development** (Clinical Oncology Representative): Team member activities, with evaluation of small molecules tyrosine kinase inhibitors, biologics, cytotoxic agents, immunomodulatory agents, diagnostic, and device opportunities.
10. **Target Selection Committee** (Clinical Oncology Representative): Team member with evaluation of proposed targets for initial drug discovery efforts; cross-functional assessment of targets suitable for biological therapeutics approach.
11. **Company Activities:** Participation in activities in support of Company-wide projects and priorities, including internal committees for human resources and integration activities with AstraZeneca.
12. **Professional Training Activities**
  - a. Facilitate Oncology Leaders' Forum 2007 – Boston, MA Nov07
  - b. PERI – Biologics Drug Development: An Integrated Overview of Manufacturing, Nonclinical, Clinical, and Regulatory Requirements. Washington DC, Apr08
  - c. 3<sup>rd</sup> Annual Trial Design Innovation: Accelerating Safer Drug, Device and Biologic Development with Adaptive Trials. Washington DC, Jul08.
  - d. Industry Perspective on Clinical Safety and Pharmacovigilance, Gaithersburg, MD Nov08.
  - e. Martell Communications, February 2012 – Executive communications Training.
13. **Regulatory Agency Experience:**
  - a. Birinapant (TL32711) – Ongoing clinical research program, FDA INDs of September 2009, February 2013, August 2013
  - b. MEDI-538: Resolution of Clinical Hold to initial IND filing in Aug06, with subsequent Successful IND application Feb07.
  - c. MEDI-561: Approval of FDA orphan drug application for GIST in Sept07

- d. MEDI-561: Approval of EMEA orphan drug application for GIST in Oct07
- e. MEDI-561: Successful IND application for IPI-504 in Oct07
- f. MEDI-561: End-of Phase 1 FDA meeting Dec07
- g. MEDI-561: FDA SPA submission for GIST Phase 3 trial proposal Feb08, approval Apr08
- h. MEDI-561: EMEA SA submission for GIST Phase 3 trial proposal Feb08,approval May08
- i. MEDI-561: IMPD submission for HER2+ Breast Cancer Phase 2 trial proposal Feb08
- j. MEDI-547: FDA Pre-IND meeting Feb08
- k. MEDI-547: Successful IND application Dec08.
- l. MEDI-547 EMEA Orphan Drug Application
- m. MEDI-547 FDA Orphan Drug Application
- n. MEDI-565 FDA Type B Pre-IND Meeting

***Clinical Research Experience:***

1. A Pilot Study of Paclitaxel/Cyclophosphamide and High Dose Melphalan/Etoposide with Autologous Progenitor Cell Transplantation for the Treatment of Metastatic and High Risk Breast Cancer. 1997-98.
2. Pilot Study of Autologous T Cells and/or IL-2 for the Enhancement of Immune Reconstitution after Dose-Intensive Chemotherapy for Breast Cancer, 1997-98.
3. IRB 2884 Phase 2 Trial of Adoptive Immunotherapy of Advanced Renal Carcinoma and Melanoma with Tumor-Primed, Ex Vivo Activated T Lymphocytes. 1998-present. Co-Investigator. Cleveland Clinic Foundation. Cleveland, OH.
4. IRB 3809 - Angiozyme™:A safety and biological efficacy study of multidose Angiozyme™ in patients with refractory solid tumors - clinical and biological modulatory effects following daily subcutaneous administration. 1999-present.
5. IRB 3608 - A Phase 2 Trial of Neoadjuvant Paclitaxel, Cisplatin and Concurrent Accelerated Fractionation Radiation followed by Adoptive Immunotherapy with Tumor-Primed Ex-vivo Activated T-Lymphocytes for Stage III Non-small Cell Lung Cancer. 2000.
6. Southwest Oncology Group -participating investigator. IRB 3884 - Generation of dendritic cells from monocytes obtained from peripheral blood mononuclear cells (PBMC) leukapheresis samples of normal adult volunteers and adult patients with cancer.
7. IRB 4050 - A phase II, open label, multi-center trial of ANGIOZYME, a ribozyme inhibitor of VEGFR-1 in patients with metastatic breast cancer who have failed at least one course of chemotherapy for metastatic disease.
8. IRB 4404 - A phase 1/2 study of active immunotherapy of stage III/IV melanoma with chimeric hybrids generated by electrofusion of autologous dendritic cells and allogeneic melanoma cell lines (CancerVax).
9. IRB 6000 - Generation of Tumor Cell Lines from Adult Patients with Cancer, Co-investigator, Cleveland Clinic Foundation.
10. IRB 6292 - Early Stage Breast Cancer Patients Treated with Conservation Surgery between 1975-1988.
11. IRB 6589 - A Phase 2 Study of Intravenous Edotecarin (PHA-782615) in Patients with Anthracycline- and Taxane-Resistant Metastatic Breast Cancer.
12. IRB 6890 - B-type natriuretic peptide as a potential marker for

- chemotherapy-induced cardiotoxicity in cancer patients receiving doxorubicin.
13. NIH CA77091-04, (Competitive Renewal 12/01/04 - 11/30/09) Telomeres, telomerase and chemotherapy: Bench to bedside.
  14. Avon Foundation 2004 - A Phase 1/2 Study of Suramin in Combination with Paclitaxel in Advanced (Stage IIIB or IV) Metastatic Breast Cancer. Co-investigator.
  15. Cleveland Clinic Foundation Renal SPORE Grant Application 2004. Project 5 : Metalloproteinases as an early detection marker in renal cell carcinoma.
  16. IRB 7421- Phase 2 multicenter, open-label , non-randomized study of intravenous RPR 109881 q 3 weeks in patients with metastatic breast cancer progressing after therapy with anthracyclines, taxanes and capecitabine.
  17. IRB 7518 - A randomized, double-blind, placebo controlled study to evaluate AMG 162 in the treatment of bone loss in subjects undergoing aromatase inhibitor therapy for non-metastatic breast cancer.
  18. IRB 7608 - A phase 1/2 study of active immunotherapy of stage III and IV melanoma with chimeric hybrids of autologous dendritic cells and tumor cells generated by electrofusion.
  19. IRB 7635 - Identification and Validation of a Prognostic Signature for Local Recurrence in Early Stage Breast Cancer.
  20. IRB 7687 - Correlative Clinical Histories of Patients from the Breast Cancer Information System with Stored Tumor Tissue.
  21. IRB 7961 - Breast cancer in young women less than 40years: the Cleveland Clinic Experience. Principal investigator
  22. IRB 7965 - Dynamic infrared imaging to monitor response to primary systemic chemotherapy for breast cancer.
  23. IRB 8245 - A phase 1/2 study of suramin in combination with paclitaxel in advanced (stage IIB or IV) breast cancer.
  24. IRB 8290 - Molecular and clinical characterization of BRCA positive versus BRCA negative breast cancers
  25. MI-CP137 – A phase I multicenter, open-label, single-arm dose-escalation study to evaluate the safety, tolerability, and antitumor activity of continuous intravenous infusion of the bispecific t-cell engager MEDI-538 in adults with B-cell non-Hodgkin’s lymphoma not eligible for curative therapy.
  26. MI-CP 155 – A phase 1/2, open-label, single-arm, dose-escalation study to evaluate the safety, tolerability and antitumor activity of continuous intravenous infusion of the bispecific T-cell engager MEDI-538 in adults with B-cell chronic lymphocytic leukemia (B-CLL) who have minimal residual disease following previous therapy for B-CLL.
  27. MI-CP153 - A phase 2 open-label, single arm study to evaluate the safety, tolerability and anti-tumor activity of biweekly infusion of MEDI-561, a small molecule inhibitor of Hsp90, in women with HER-2/neu over-expressing (Her2+) breast cancer who have progressed despite prior trastuzumab-based therapy.
  28. MI-CP159 – A phase 2, Open-label, single-arm, multicenter study evaluating the safety and antitumor activity of IPI-504, a novel small molecule inhibitor of heat shock protein 90 (Hsp90), in patients with metastatic melanoma.
  29. MI-CP160 - A phase 2, open-label, single-arm, multicenter, multinational study to evaluate the antitumor activity and safety of IPI-504, a novel small molecule inhibitor of heat shock protein 90 (Hsp90), in patients with locally advanced or metastatic human epidermal growth factor receptor 2-positive (HER2+) breast cancer who have no prior treatment with HER2-targeted therapies for advanced disease, or greater than 1 year duration since completion of HER2-targeted therapies for adjuvant therapy of local disease.

30. MI-CP171 – A phase 3 randomized, double-blind, placebo-controlled, multicenter study evaluating the efficacy and safety of IPI-504 in patients with at least imatinib- and sunitinib-resistant or –intolerant gastrointestinal stromal tumors.
31. MI-CP177 – A phase 1, open-label, single-arm, dose-escalation study to evaluate the safety, tolerability, pharmacokinetics, and biologic activity of MEDI-547, a humanized monoclonal antibody conjugated to monomethyl auristatin phenylalanine, directed against the epithelial tyrosine kinase receptor EphA2, in patients with refractory solid tumors associated with EphA2 expression.
32. TL32711-FIH-007-PTL - A Phase 1, Open-Label, Non-randomized, Dose Escalation Study of the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of TL32711 in Adults with Refractory Solid Tumors or Lymphoma
33. TL32711-POC-0078-PTL - A Phase 1B/2A, Open-label, Non-randomized, Multi-arm Study of TL32711 in Combination with Chemotherapy in Subjects with Advanced or Metastatic Solid Tumors
34. RPCI # I 210811 -A Phase I study of TL32711 in combination with gemcitabine in patients with advanced solid tumors
35. UPCC#15411- A Phase I-II Open-label non-randomized study using TL32711 For patients with Acute Myelogenous Leukemia.
36. NCI#9235 - Phase II Open Label Non-Randomized Single Agent Study of the SMAC (Second Mitochondrial-Derived Activator of Caspases)-Mimetic Birinapant (TL32711; NSC 756502) in Relapsed Platinum Resistant or Refractory Epithelial Ovarian Cancer, Primary Peritoneal Cancer or Fallopian Tube Cancer
37. TL32711-POC-0087-PTL-Protocol. A Phase 1b/2a, Open-label, Non-randomized Study of Birinapant in Combination with 5-azacitidine in Subjects with Myelodysplastic Syndrome who are Naïve or are Refractory or have Relapsed to 5-azacitidine Therapy.
38. TL32711-POC-0090-PTL. A Phase 1b, Open-label, Non-randomized Multicenter Study of Birinapant in Combination with Conatumumab in Subjects with Relapsed Epithelial Ovarian Cancer, Primary Peritoneal Cancer or Fallopian Tube Cancer

***Research Funding Experience:***

1. Cleveland Clinic Foundation, Taussig Cancer Center Translational Therapeutics Research Award Active (2/1/00) - “Preclinical translation of COX-2 inhibitor treatment as an adjunct to conventional immunotherapy”. Principal Investigator: Peter A. Cohen, M.D.; Co-investigator: David E. Weng, M.D.,Ph.D.
2. Don Shula Foundation, Inc. (4/27/00) “Adoptive Immunotherapy of Breast Cancer”. Principal investigator: Julian A. Kim, M.D., Co-investigator David E. Weng, M.D.,Ph.D.
3. Ribozyme Pharmaceuticals Inc.(5/16/00). “Angiozyme Translational Research Award- Inhibition of Flt-1 expression as an anti-tumor strategy in the murine 4T1 model system for metastatic breast carcinoma”. Principal Investigators: Julian A. Kim, M.D., Co-investigator: David E. Weng, M.D.,Ph.D.,
4. NIH-RO1 Grant (2000) - CD8+ helper-independent T cells in tumor therapy. Principal Investigator: Peter A. Cohen. M.D; Co-Investigator: David E. Weng, M.D.Ph.D.
5. Lynne Cohen Foundations (5/2001) - Preclinical Studies of Adoptive Immunotherapy for Advanced Ovarian Cancer. Principal Investigator: David E. Weng, MD.PhD.
6. NIH CA77091-04, (Competitive Renewal 12/01/04 - 11/30/09) Telomeres, telomerase and chemotherapy: Bench to bedside. Principal Investigator:Jessie L.S.

- Au, Ph.D., Consultant - David E. Weng, MD.Ph.D.
7. Avon Foundation 2004 - A Phase I/II Study of Suramin in Combination with Paclitaxel in Advanced (Stage IIIB or IV) Metastatic Breast Cancer. Principal Investigator: Charles Shapiro, MD, Co-investigator - David E. Weng, MD, Ph.D.
  8. Advanced Biophotonics, Inc, 2005 - Preoperative chemotherapy Monitoring Study, Principal Investigator- David Weng, MD,Ph.D.

***Awards:***

- 1980 - High School Valedictorian, Rochester Adams High School
- 1980 - National Merit Scholar
- 1981-1984 - Harvard College Scholar
- 1984 - Medal of Charles Eliot (Community Service Award)
- 1984 - A.B. Magna cum laude, Biochemical Sciences,
- 1985-1992 - Medical Scientist Scholar of the Life and Health Insurance Medical Research Fund
- 1992 - Hartford Foundation Clinical Scholar in Geriatric Medicine
- 1993 - NIH Research Festival Clinical Trainees Research Award
- 1995 - Osler House Staff Award "Most Aequanimitas Resident"
- 1995-98 - U.S. Public Health Service Commissioned Corps, Lt. Cmdr
- 1995-98 - Chief Fellow, National Cancer Institute Medicine Branch
- 1998 - Joint AACR/ASCO Conference, "Methods in Clinical Cancer Research"
- 2001 - Northern Ohio Breast Cancer Coalition - Certificate of Appreciation
- 2001 - Cuyahoga County Commissioners - Certificate of Appreciation -2001 Breast and Cervical Cancer Treatment Program
- 2001 - The Ohio State Senate - Special Recognition Citation - 2001 Breast and Cervical Cancer Treatment Program
- 2006 – George Crile, Jr. M.D. Award, Northern Ohio Breast Cancer Coalition, Excellence in Patient Care and Advocacy.

***Military/Government Service:***

- 1995-98 U.S. Public Health Service, Commissioned Corps.

***Professional Societies/Committees:***

- American College of Physicians
- American Society for Clinical Oncology
- American Society for Hematology
- American Association for Cancer Research
- American Medical Association
- Johns Hopkins Medical and Surgical Association

***Certifications:***

- State of California Medical License (2013-present)
- State of Maryland Medical License (1995-present)
- State of Ohio Medical License (1998-present)
- State of California Medical License (2013- pending)
- Federal DEA Licensure for Controlled Substances (1996-present)
- ABIM Diplomate, Internal Medicine (1995-2005)
- ABIM Diplomate, Medical Oncology (1997 - present)

***Journal Editorship/Reviewer Experience:***

- Current Oncology Reports - Literature Review Editor, 1998-2001
- Ad hoc Reviewer, Journal of Clinical Investigation
- Ad hoc Reviewer, Cancer Immunology and Immunotherapeutics
- Ad hoc Reviewer, Cancer Research
- Ad hoc Reviewer, Journal of Interferon and Cytokine Research
- Ad hoc Reviewer, Cancer

***Grants Reviewer Activity Experience:***

- United States Veterans Administration Medical Research Program
- Department of Defense, Congressionally Directed Medical Research Programs, Breast Cancer Research Program

***Invited Talks:***

1. 10/29/99 - CCF Taussig Cancer Center Grand Rounds Presentation: IRB 3309 -“A safety and biological efficacy study of multidose angiozyme in patients with refractory solid tumors, Cleveland , OH.
2. 5/10/00 - CCF Medicine Residents Noon Conference Talk - New Developments in Cancer Therapeutics, Cleveland, OH
3. 8/16/00 - Cleveland Clinic Foundation, Department of Otolaryngology - “Current Status of Angiogenesis Inhibitors in Cancer Therapeutics”, Cleveland, OH
4. 8/19/00 - Pittsburgh Community Oncology - “Advances in the Treatment of Metastatic Breast Cancer”, Pittsburgh, P{A
5. 10/20/00 - VIII Congress of the Dominican Society of Hematology and Oncology - “Adjuvant Therapy for Breast Cancer”, Santo Domingo, Dominican Republic.
6. 10/20/00 - VIII Congress of the Dominican Society of Hematology and Oncology - “Novel Approaches for the Therapy of Advanced Breast Cancer”, Santo Domingo, Dominican Republic
7. 10/28/00- Northern Ohio Breast Cancer Coalition Foundation - “Progress and Hope”, Cleveland, OH
8. 12/8/00 - The Moll Cancer Center Grand Rounds - “Genetics and Biology of Cancer”, Fairview Park, OH
9. 1/20/01 - 3rd International Symposium on Anti-Angiogenic Agents - Angiozyme: Clinical development of a novel ribozyme-based angiogenesis inhibitor. Dallas TX
10. 3/16/01 - Advances in the Treatment of Metastatic Breast Cancer - Tampa Area Community Oncology, Tampa , FL
11. 5/2/01 - New Therapeutic Approaches in the Management of Breast Cancer - Taussig Cancer Center, Cleveland ,OH
12. 6/7/01 - ASCO 2001 Update in Breast Cancer - Central Pennsylvania Oncology Group, Harrisburg, PA
13. 6/9/01 - Tumor-Dendritic Cell Fusion Approaches to Immunotherapy. Gene Therapy Subcommittee of the Annual Meeting of the Eastern Cooperative Oncology Group, Pittsburgh, PA.
14. 7/17/01 -Taussig Cancer Center Grand Rounds. CCF
15. 10/20/01 - Research Frontiers in Medical Oncology, Northern Ohio Breast Cancer Coalition Symposium, Cleveland, OH
16. 11/11/01 - ANGIOZYME, a Synthetic Ribozyme Targeting the mRNA of VEGFR-1: Clinical Update, 16<sup>th</sup> Annual Meeting for the Society for Biological Therapy, Bethesda, MD.
17. 1/11/2002 - 4<sup>th</sup> International Symposium on Anti-Angiogenic Agents. Dallas, TX.
18. 2/23/2002 - 5<sup>th</sup> Annual Regional Cancer Center Consortium for the Biological Therapy of Cancer. Cleveland, OH



19. 3/7/2002 - University of Michigan, Division of Surgical Oncology, Ann Arbor, MI
20. 5/8/2002 - Columbus Community Oncology, Columbus, OH.
21. 7/9/2002 - Taussig Cancer Center Grand Rounds, Cleveland, OH.
22. 10/05/2002 - Northern Ohio Breast Cancer Coalition Fund 3<sup>rd</sup> Annual Breast Cancer Symposium., Cleveland, OH.
23. 04/2/03 - “Advances in the Treatment of Metastatic Breast Cancer”. Minneapolis Community Oncology, Minneapolis, MN
24. 04/23/03 - “Advances in the Treatment of Metastatic Breast Cancer” University of Minnesota, Minneapolis, MN
25. 09/10/2003 - “Advances in the Treatment of Metastatic Breast Cancer” Kaiser Permanente Oncology, Cleveland OH
26. 10/28/03 - Taussig Cancer Center Grand Rounds, Cleveland, OH
27. 11/19/03 - “Hormonal Therapy Management Strategies in Breast Cancer”, Cleveland, OH.
28. 3/16/04 - CCF Internal Medicine Residents Noon Conference - “Breast Cancer - 2004”, Cleveland, OH
29. 4/23/04 - University of Kentucky - “Management of Metastatic Breast Cancer. Lexington, KY
30. 5/22/04 - Multidisciplinary Approach to Breast Cancer: A Forum for Trainees in Medical Oncology, Surgery, Radiation Oncology, and Radiology, Cleveland, OH 44195
31. 6/17/04 - Firelands Regional Medical Center Grand Rounds - “Molecular Approaches in Breast Cancer.”, Pittsburgh, PA
32. 7/1/04 - Cleveland Clinic Foundation ASCO Review 2004, Cleveland, OH
33. 8/4/04 - Mt. Sinai Medical Center - Oncology Center Grand Rounds, Baltimore, OH.
34. 8/4/04 - Mercy Medical Center - Breast Tumor Board Rounds, Baltimore, OH
35. 9/29/04 - Mercy Health Partners - Oncology Services Meeting, Toledo, OH
36. 10/22/04 - The Leukemia and Lymphoma Society - Cancer in the Classroom program, Beachwood, OH.
37. 11/2/04 - Genomic Health Preceptorship, Cleveland, OH
38. 11/3/04 - American College of Surgeons, South Florida Chapter Meeting, West Palm Beach, FL
39. 11/4/04 - Florida Hospital Cancer Institute Multidisciplinary Tumor Board , Orlando, FL
40. 1/14/05 - Integris Baptist Hospital Oncology Grand Rounds, Oklahoma City, OK
41. 1/25/05 - Grand Rapids Regional Oncology - Highlights of 2004 San Antonio Breast Cancer Symposium, Grand Rapids, MI
42. 2/9/05 - Cleveland Clinic Foundation - Best of 2004 SABCS, Independence, OH
43. 2/19/05 - Grand Blanc Oncology - Highlights of 2004 SABCS , Grand Blanc, MI
44. 2/22/05 - Cornell University Tumor Board, New York Hospital, New York City, NY
45. 3/10/05 - Summa Health Systems Tumor Board, Akron, OH
46. 4/12/05 - Overview of Hormonal Therapies for Breast Cancer, Cleveland OH.
47. 4/18/05 – Community Oncology CME, Indianapolis, IN
48. 4/29/05 - Lehigh Valley Hospital Tumor Board - Allentown, PA
49. 5/9/05 - Harper Hospital Tumor Board - Detroit, MI
50. 5/18/05 - Overview of Hormonal Therapies for Breast Cancer, Canton, OH
51. 6/2/05 - Waterloo Community Oncology, Educational Concepts CME, Waterloo, IA
52. 6/10/05 - CCF Intensive Review of Internal Medicine Board Review, Cleveland, OH
53. 6/23/05 - Fairfax Hospital, CME, Fairfax, VA
54. 6/29/05 - Jacksonville Community Oncology CME, Jacksonville, FL
55. 7/19/05 - Trumbull Memorial Hospital CME, Warren, OH

56. 8/3/05 - Roger Maris Cancer Center CME, Fargo, ND
57. 8/17/05 - Montgomery Community Oncology CME, Montgomery, AL
58. 8/18/05 - Pensacola Oncology CME, Pensacola, FL
59. 9/1/05 - US Oncology CME, Albany, NY
60. 9/15/05 - Bakersfield Community Oncology CME, Bakersfield, CA
61. 9/22/05 - Providence Oncology CME, Providence, RI
62. 10/8/05 - Ohio/West Virginia Oncology Association CME, Columbus, OH
63. 10/12/05 - Chattanooga Community Oncology CME, Chattanooga, TN
64. 11/1/05 - Community Oncology CME, Boulder, CO
65. 11/2/05 - Community Oncology CME, Salt Lake City, UT
66. 11/3/05 - Community Oncology CME, Hutchinson, KS
67. 11/9/05 - Community Oncology CME, Lexington, KY
68. 11/10/05 - Community Oncology CME, Evansville, IN
69. 11/16/05 - Community Oncology, CME, Covington, KY
70. 11/17/05 - Community Oncology CME, Boston, MA
71. 11/30/05 - Community Oncology CME, Flushing, MI
72. 12/1/05 - Community Oncology CME, Kansas City, MO
73. 1/12/06 - Miami Valley Hospital, SABCS 2005 Review CME, Dayton, OH
74. 1/25/06 - Community Oncology CME, Cleveland, OH
75. 2/8/06 - Cleveland Clinic Foundation SABCS 2005 Review CME, Cleveland, OH
76. 2/9/06 - Community Oncology CME, Oklahoma City, OK
77. 2/16/06 - Community Oncology CME, Albuquerque, NM
78. 2/23/06 - Community Oncology CME, Louisville, KY
79. 2/25/06 - 7<sup>th</sup> Annual Health Care Forum, Blount County Medical Society CME, Oneonta, AL
80. 3/1/06 - Long Island Oncology Network SABCS 2005 Review CME, Long Island, NY
81. 3/9/06 - New York City Community Oncology CME, New York, NY
82. 4/12/06 - Columbus Community Oncology CME, Columbus, OH
83. 4/13/06 - SUNY Upstate Medical Center Grand Rounds, Syracuse, NY
84. 4/21/06 - Abraxis Oncology Advisory Board, San Antonio, TX
85. 5/12/06 - US Oncology Executive P&T Committee Presentation, Dallas, TX
86. 5/24/06 - Community Oncology CME, Lancaster PA
87. 5/31/06 - Oncology Grand Rounds, Pardee Hospital, Hendersonville, NC
88. 6/22/06 - Community Oncology CME, Springfield, MA
89. 6/29/06 - Community Oncology CME Columbia, SC
90. 6/30/06 - Community Oncology CME, Elizabethtown KY
91. 8/10/06 - Community Oncology CME, Colorado Springs, CO
92. 8/23/06 - Community Oncology CME, Rockford, IL
93. 8/24/06 - Community Oncology CME, Rosemont, IL
94. 8/29/06 - Community Oncology CME, Asheboro, NC
95. 9/7/07 - MedImmune Company-wide Presentation of Hsp90 Inhibitor Program, Gaithersburg, OH
95. 2/8/08 - Breast Cancer Genetics and Predicting Cancer Recurrence, Cleveland OH
96. 10/20/2010 - Zhongguancun Forum 2010, Beijing China.
97. 12/1/11 - Mid-Atlantic Bio Conference, Gaithersburg, MD
98. 3/6/12 - Defined Health - 23<sup>rd</sup> Annual Cancer Progress Conference, NYC, NY
99. 2/21/13 - "Pipelines in Oncology", Dana-Farber/Massachusetts General Hospital Cancer Center. Boston, MA

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1. Gordon, G.B., Newitt, J.A., Shantz, L.M., Weng, D.E. and P. Talalay (1986). Inhibition of the conversion of 3T3 fibroblast clones to adipocytes by dehydroepiandrosterone and related anticarcinogenic steroids. *Cancer Research* 46, 3389-3395.
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3. Weng, D.E. and J.W. Littlefield (1991). Loss of expression of the uvomorulin gene in compaction-defective H6 embryonal carcinoma cells. *Somatic Cell and Molecular Genetics*, 17, 617-619.
4. Urven, L.E., Weng, D.E., Schumaker, A.L., Gearhart, J.D., and J.R. McCarrey. (1993) Differential gene expression in fetal mouse germ cells. *Biol.Reproduction*, 48, 564-574.
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7. Weng, D.E., Wilson WH, Little R, and T. Walsh. (1998) Successful Medical Management of Isolated Renal Mucormycosis: Case report and review of the literature. *Clin Infect Dis.* 26, 601-5.
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10. Plautz GE, Weng DE, Kim JA, Cohen PA, Shu S (1999) Preclinical development and clinical experience with T cell adoptive immunotherapy of cancer. *Recent Res Devel Cancer* 1:163-179.
11. Fetsch PA, Cowan K, Weng DE, Filie A, Abati A.(2000) Detection of circulating tumor cells and micrometastases in Stage II, III and IV breast cancer patients utilizing cytology and immunocytochemistry. *Diagnostic Cytopathology* 22, 323-328.
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2. Coordinated Expression of Members of the jun Family During Early Embryogenesis in the Mouse. Cold Spring Harbor Laboratory, Molecular Genetics of the Mouse, August 29, September 2, 1990.
3. Gene Expression in Mouse Primordial Germ Cells Detected by cDNA Library Analysis. Gordon Conference, Mammalian Gametogenesis and Embryogenesis. Gordon Conference, July 30-August 2, 1990.
4. Targeted Disruption of the Insulin Receptor Gene in ES cells. Wind River (CO) Conference on Genetic Exchange. June, 1991.
5. Cell Type-Specific Gene Expression in Fetal Mouse Gonads. Society for the Study of Reproduction. August, 1991.
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7. Increased susceptibility to apoptosis in CD4 cells post autologous transplantation. American Society for Hematology, 1997.
  8. Detection of Circulating Tumor Cells and Micrometastases in Stage II, III and IV Breast Cancer Patients using Immunocytochemistry (1999) United States and Canadian Academy of Pathology.
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  24. Fanning SR, Short S, Coleman K, Andresen S, Budd GT, Moore A, Rim A, Crowe J, Weng DE (2006). Correlation of dynamic infrared imaging with radiologic and pathologic response for patients treated with primary systemic therapy for locally advanced breast cancer. ASCO 2006 .
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  27. Budd GT, Tubbs RR, Crowe J, Weng D, Moore H, Cook R, Swain E, Prescott N, Pettay J, Tarr S, Hicks D. (2006 ) Neoadjuvant chemotherapy of operable breast cancer with single-agent epirubicin: efficacy and predictive factors for response. SABCs 2006.
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  31. Wesolowski R, Choueiri TK, Rybicki L, Shealy AG, Casey G, Weng D, Moore HCF (2007). *BRCA* Mutation Status And Risk Of Secondary Malignancy Following Chemotherapy For Breast Cancer. ASCO 2007
  32. Leow CC, Coffman K, Chesebrough J, Mao S, Fazenbaker C, Gooya J, Weng D, Porter J, Coats S, Jallal B, Jackson D, Chang YS. (2007) IPI-504, a selective inhibitor of Hsp90, exhibits potent antitumor activity against *HER2*<sup>+</sup>, trastuzumab(Herceptin) –sensitive and –refractory cell lines. AACR-NCI-EORTC Molecular Targets and Cancer Therapeutics. Abstract #B225.
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  34. AACR Annual Meeting 2011 (Abstract LB-406) - Phase 1 study of the Smac mimetic TL32711 in adult subjects with advanced solid tumors and lymphoma to

- evaluate safety, pharmacokinetics, pharmacodynamics, and antitumor activity. Ravi K. Amaravadi, Russell J. Schilder, Grace K. Dy, Wen W. Ma, Gerald J. Fetterly Jr., David E. Weng, Martin A. Graham, Jennifer M. Burns, Srinivas K. Chunduru, Stephen M. Condon, Mark A. McKinlay, Alex A. Adjei. *Cancer Research* July 12, 2011 71:LB-406; doi:10.1158/1538-7445.AM2011-LB-406
35. ASH Annual Meeting 2011 (Abstract 604) Antagonizing IAPs by SMAC Mimetic TL32711 Induces Apoptosis in AML Cells Including AML Stem/Progenitor Cells Alone and in Combination with Chemotherapy. Bing Z Carter, Ph.D., Duncan H Mak, M.S., Yihua Qiu, Steven M. Kornblau, MD, Po Yee Mak, MS, David Weng, Mark A McKinlay and Michael Andreeff, M.D., Ph.D.
  36. ASCO Annual Meeting 2012 (Abstract 3029)- Clinical pharmacokinetics of the Smac-mimetic birinapant (TL32711) as a single agent and in combination with multiple chemotherapy regimens. Gerald J. Fetterly, Biao Liu, Neil N. Senzer, Ravi K. Amaravadi, Russell J. Schilder, Lainie P. Martin, Patricia LoRusso, Kyriakos P. Papadopoulos, Alex A. Adjei, Patricia D. Zagst, Mark A McKinlay, David Edward Weng, Martin Graham. - *J Clin Oncol* 30, 2012 (suppl; abstr 3029)
  37. AACR Annual Meeting 2012 (Abstract 3857) Smac mimetic TL32711 and TRAIL synergistically induce apoptosis of germinal center B lymphoma cells. Mitchell R. Smith, Indira Joshi, David E. Weng, Srinivas Chunduru, Mark A. McKinlay
  38. AACR Annual Meeting 2012 (Abstract 1939). TL32711, a novel Smac mimetic, exerts significant antitumor efficacy in primary pancreatic adenocarcinoma model. Wen Wee Ma, Hao Zhang, Bonnie Hylander, Charles LeVe, Elizabeth Repasky, David Weng, Jennifer Burns, Srinivas Chunduru, Martin Graham, Gerald Fetterly, Mark McKinlay, Alex Adjei.
  39. AACR Annual Meeting 2013 (Abstract 3336). The Smac Mimetic Birinapant Synergistically Induces Apoptosis in Combination with Type I Interferons and GM-CSF. Christopher A. Benetatos, Jennifer M. Burns, Ernest C. Borden, Daniel Lindner, Yasuhiro Mitsuuchi, Mark A. McKinlay, Gurpreet Singh Kapoor, Eric M. Neiman, Martin E. Seipel, Guangyao Yu, Martin Graham, David Weng, Stephen M. Condon, C. Glenn Begley and Srinivas K. Chunduru. *Cancer Research* August 14, 2013 73:3336; doi:10.1158/1538-7445.AM2013-3336
  40. AACR Annual Meeting 2013 (Abstract 3333) Birinapant, a Novel Bivalent SMAC Mimetic Drug, is Superior to Monovalent SMAC Mimetics in Inhibition of NF- $\kappa$ B by Targeting TRAF2-bound cIAP1 and cIAP2 Y. Mitsuuchi, S. M. Condon, E. M. Neiman, C. A. Benetatos, M. E. Seipel, G. S. Kapoor, A. C. Mufalli, G. Yu, O. Maguire<sup>2</sup>, H. Minderman<sup>2</sup>, M. A. McKinlay, M. Graham, D. Weng<sup>1</sup>, and S. K. Chunduru.
  41. ASCO Annual Meeting 2013 (Abstract 2504). A Phase 1 Study of Birinapant (TL32711) Combined with Multiple Chemotherapies Evaluating Tolerability and Clinical Activity for Solid Tumor Patients. R. Amaravadi, N. Senzer, L. Martin, R. Schilder, P. LoRusso, K.P. Papadopoulos, M. Graham, D. Weng, A. A. Adjei. *J Clin Oncol* 31, 2013 (suppl; abstr 2504)
  42. ASCO Annual Meeting 2013 (Abstract 3621). Clinical Activity and Tolerability of the SMAC-mimetic Birinapant (TL32711) plus Irinotecan in Irinotecan-relapsed/refractory Metastatic Colorectal Cancer. N. Senzer, P. LoRusso, L. Martin, R. Schilder, R. Amaravadi, K.P. Papadopoulos, Z. Segota, M. Graham, D. Weng., A. A. Adjei. *J Clin Oncol* 31, 2013 (suppl; abstr 3621)
  43. ASCO Annual Meeting 2014 (Abstract submitted). Pharmacodynamic biomarkers from Phase 2 Study of SMAC (Second Mitochondrial-Derived Activator of Caspases)-Mimetic Birinapant (TL32711; NSC 756502) in Relapsed Platinum

Resistant Epithelial Ovarian Cancer (EOC), Primary Peritoneal Cancer (PPC), or Fallopian Tube Cancer (FTC) (NCT01681368). C. Annunziata et al.

*References available on request.*



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*Venture capitalist with 30 years of investing, pharma licensing and scientific experience.  
Track record of identifying promising investments and working effectively with company management  
and co-investors to drive value creation.*

*Key leader in venture partnership, active in deal sourcing and portfolio management  
as well as experienced with independent and corporate venture fund administration.*

### **PROFESSIONAL EXPERIENCE:**

#### **PFIZER VENTURE INVESTMENTS (New York, NY)**

**2008 - present**

##### **Executive Director**

Managing biotechnology and healthcare investments for Pfizer. Responsible for identifying, assessing, and making investments in platform technology and drug discovery and development companies. Led or co-led 8 investments to-date and currently managing investments in **Aquinox** (Vancouver, BC), developing novel anti-inflammatory drugs; **Autifony** (London, UK), advancing new treatments for hearing loss; **Flexion** (Woborn, MA), a specialty pharma company focused on new injectable treatments for osteoarthritis; **Mersana** (Cambridge, MA) developing antibody-drug conjugates; **Merus** (Utrecht, Netherlands), developing a biologics platform for oligoclonic antibody production from a single cell; **MISSION Therapeutics** (Cambridge, UK) identifying new targets for anti-cancer therapies in the DNA repair pathway; **Neuronetics** (Malvern, PA), commercializing NeuroStar TMS Therapy, a non-invasive, non-systemic treatment for depression; and **TetraLogic** (Malvern, PA) developing SMAC mimetics for cancer therapy. Strong relationships in biotechnology community and with other life science investors.

#### **EUCLIDSR PARTNERS (New York, NY)**

**2000 - 2008**

##### **General Partner**

Partner in \$250M venture capital fund focused in life sciences, information technology and convergence. Identified, evaluated, and made biotechnology and healthcare IT investments, including PIPEs. Responsible for actively managing investments in **Acurian**, Inc. (Horsham, PA), a patient recruitment solutions provider; **Fluidigm** (NASDAQ: FLDM; San Francisco, CA), a microfluidics company developing tools for the life science research and molecular diagnostic markets; **InnaPhase** Corp. (Phila, PA), a pharma-focused LIMS company which was sold to Thermo Electron in 2004; lead investor and first Board Chair of **Targacept**, Inc. (NASDAQ: TRGT; Winston-Salem, NC), a company focused on therapeutics targeting neuronal nicotinic receptors for nervous system diseases; and **Vivus** (NASDAQ: VVUS; Mountain View, CA), a company developing treatments for obesity and sexual health.

#### **SR ONE (West Conshohocken, PA)**

**1999 - 2003**

##### **Vice President**

**2001 - 2003**

##### **Investment Manager**

**1999 - 2001**

Managed biotechnology investments for SR One, GSK's \$100M venture capital subsidiary. Key driver on 10 investments, including **Adolor** Corporation (NASDAQ: ADLR, Exton, PA); **Avantium** International (previous Chair, Amsterdam, The Netherlands); **Scynexis** (RTP, NC); and **Vicuron** (NASDAQ: MICU, King of Prussia, PA).

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**SMITHKLINE BEECHAM (Upper Merion, PA)**

**1984 - 1999**

**Director, Scientific Licensing**

**1994 - 1999**

Responsible for identifying product opportunities and coordinating due diligence in therapeutic areas of rheumatoid arthritis, osteoarthritis, osteoporosis, urology and oncology. Negotiated license agreements for several major product acquisitions and platform technologies (Coulter, Immunogen). Developed proposals and completed deal for out-licensing SB products and technologies (Invitrogen). Frequent interactions with senior R&D management to set strategy and develop / implement in-licensing action plans. Developed substantial network throughout biotechnology industry.

**Research Manager, Molecular Biology, SB Animal Health**

**1987 - 1994**

Led research group using genetic engineering to clone and express viral, bacterial and parasitic antigens for development of animal vaccines. Responsible for recommending new research and development strategies. Directed two research projects. Evaluated new technologies under consideration for in-licensing. Responsible for establishing and maintaining collaborations with top scientists in key areas of research.

**Associate Senior Investigator, Molecular Genetics,  
SKF Laboratories**

**1984 - 1987**

Key liaison between SKF Molecular Biology department and SB Animal Health R&D (Lincoln, NE). Responsible for generating vaccine antigens using genetic engineering technologies. Established recombinant vaccinia virus technology at SKF.

**EDUCATION AND TRAINING:**

- Research Fellow      Laboratory of Viral Diseases, National Institute of Allergy and Infectious Diseases (NIAID), 1981 – 1984
- Ph.D.                      Microbiology, University of Pittsburgh School of Medicine, 1981
- B.S.                         Juniata College, *magna cum laude*, 1975

**PROFESSIONAL ACTIVITIES AND CREDENTIALS**

Education Committee Chair, Corporate Venture Capital Group Advisory Committee (2011 - )  
Member of Ben Franklin Technology Partners Bio/Life Sciences Investment Advisory Committee  
(2003 - present)

Board of Directors, Pennsylvania Biotechnology Association (1991 – 1998)

President, WIN (2008 – 2010); Board of Directors 2006 - 2011

Author of numerous scientific publications and patents/patent applications

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## Experience

Sept. 2008-  
present

### **President, Williams Cancer Drug Consulting, LLC**

- Independent oncology and regulatory consultant serving large and small oncology drug companies

2006-2008

### **Executive Director, Clinical Development, GlaxoSmithKline Pharmaceuticals**

- Chairman of oncology protocol review committee
- Clinical Development Physician in a VEGR TKI drug development team
- Voting Member of GSK Oncology Decisional Board (MDM)
- Advisor to VP of Clinical Development
- Member of PhRMA working group on progression free survival

2005-2006

### **Executive Director, Clinical Development, Novartis Pharmaceuticals**

- Chairman of oncology protocol review committee
- Clinical Development Physician for investigational drug RAD001

2002-2005

### **Deputy Director, Division of Oncology Drug Products, CDER, FDA**

- Participated in PreIND, End-of-Phase-2, and PreNDA meetings between DODP and Sponsors (often as Acting Director), providing advice on the design of pivotal trials for drug approval.
- Organized DODP management and review processes for a 43-member staff and for co-located consulting staff
- Directed hiring and training of the 15 primary medical reviewers in DODP.
- Organized the Oncology End Points evaluation process including workshops, advisory committee meetings, and draft guidance documents.  
([http://www.fda.gov/cder/drug/cancer\\_endpoints/default.htm](http://www.fda.gov/cder/drug/cancer_endpoints/default.htm)).
- First author on draft Oncology General End Points Guidance (2005)
- Member of the FDA Pharmacogenomics Working Group and Interdisciplinary Pharmacogenomics Working Group (IPRG).

1997 - 2002

### **Medical Team Leader in the Division of Oncology Drug Products**

- Served as mentor and secondary reviewer for IND and NDA submissions for a team of five medical officers. Advised Sponsors on design of pivotal trials for drug approval. Team accomplishments included review of 20 New Drug Applications or Efficacy Supplements, including approval of the Gleevec NDA in a record 2 1/2 months.
- Organized FDA working groups and authored two Guidance Documents:
  - Cancer Guidance on Clinical Data in Marketing Applications, and
  - IND Exemptions for Lawfully Marketed Cancer Drugs.

- Led a CDER Good Review Practices project to evaluate the review processes of medical officers. Constructed seven diagrams of medical officer review processes from six therapeutic areas.

1989-1996 **Medical Review Officer in the Division of Oncology Drug Products**

- Reviewed IND and NDA submissions on a large portfolio of cancer drugs including phase 1, phase 2, and phase 3 trials. Performed primary review of 14 NDAs or Efficacy Supplements including the initial approval of Taxol in 1992.
- Presented review findings to the Oncology Drugs Advisory Committee.
- Developed methods for medical officer review of electronic NDA data.

1988 - 1989 **Private practice in medical oncology**

- Private practice with Phil Roberts, M.D. in Albany, Ga.

**Education**

- 1988 Completed **fellowship in hematology and oncology**, University of Alabama at Birmingham (UAB).
- 1986 Completed **residency and internship in internal medicine**, UAB
- 1983, 1979 **Pathology fellowship**, UAB.
- 1982 Received **Medical Degree** from UAB. Graduated first in class.

**Specialty Boards**

- 1986 Internal Medicine
- 1989 Medical Oncology

**Medical Licensure:** Maryland

**Honors and Awards**

- 1973 Valedictorian, Coffee High School, Florence Alabama.
- 1982 Dempsey Scholastic Award for graduating first in medical school class at University of Alabama at Birmingham.
- 1993 Commissioner's Special Citation as member of the Taxol Review Group
- 1996 CDER award for pioneering work in use of the computer in reviewing NDA data
- 1998 Team Leader Excellence Award.
- 1998 Outstanding reviewer award for review of Photofrin supplement while functioning as team leader.
- 2001 On the spot award from Office of Drug Evaluation I for "Prolific work on Guidances."
- 2001 CDER Team Excellence Award for Gleevec Team.
- 2001 CDERs' Excellence in mentoring award: For arranging a training course for new and current staff in the Oncology Drugs Division covering all aspects of the scientific and regulatory review process.
- 2004 CDER Special Recognition Award as member of the Cancer Drug Approval Endpoints Team.

### **Invited Presentations**

1. The Review Process from the Perspective of a Medical Reviewer, The Sixth Great Lakes Symposium on Applied Statistics, Kalamazoo, Michigan, October, 2000.
2. Presentation on FDA Cancer Data Guidance to meeting of NCI, pharmaceutical representatives, and cancer cooperative group representatives, San Francisco, May 2001.
3. Presentation on Regulatory Considerations in the Design of Trials for Antiangiogenic Agents to an Expert Consensus Meeting on Clinical Trials for Antiangiogenic Therapy of Cancer, San Francisco, California, May, 2001.
4. Invited Presentation on Regulatory Consideration in Oncogenomics at AACR Oncogenomics Symposium in Phoenix Arizona, Feb 1, 2003.
5. Invited Presentation to DIA Session: Medical Review and the CRF, April 2, 2003.
6. Presentation to DIA QOL workshop on Tumor Related Symptoms and Oncology Drug Approval, April 29, 2003.
7. Presentation to Harvard-Schering Pough workshop on statistics in cancer: time to progression as an oncology endpoint. May 29, 2003.
8. Chair of Session and Presentation at Keystone Symposium on Genomic Biomarkers: Impact on Drug Discovery and Clinical Practice, Santa Fe, New Mexico, January 26 - 30, 2004.
9. Presentation to PhRMA BRMC (Bioresearch Monitoring Committee) on Monitoring and Auditing in NCI versus Industry Clinical Trials, March 11, 2004.
10. Meet the Professor's series: Drug Development and Approval in the United States, Understanding the Regulatory Process. June 5, 2004 at ASCO annual meeting.
11. Session leader at the 2004 Accelerating Anticancer Agent Development and Validation Workshop. July 13-14, 2004, Baltimore, MD.
12. Invited participant in State Specific Clinical Trial End Points for Prostate Cancer, sponsored by Prostate Cancer Foundation, held in NYC, NY, 8-16-04.
13. Speaker at AAPS Forum on Pharmacogenomics: "Impact of Genetics on Pharmacokinetics/Pharmacodynamics, Efficacy and Safety: Understanding Clinical Implications and Meeting Requirements of Regulatory Authorities, Baltimore MD, November 11, 2004.
14. Steering Committee: Pharmacogenomics in Drug Development and Regulatory Decision Making - Workshop 3, Bethesda, April 11, 2005.
15. Member of ASCO Cancer Education Committee, Health Services Resource Track, 2004-. Chair of Education Session on Endpoints for approval, ASCO Annual meeting, May, 2005.
16. DIA Panel on Evolving Global Drug Registrational Environment, June, 2006.
17. DIA Presentation on Innovative Clinical Trial Designs in Oncology, June, 2006.
18. Presentation on Accelerated Approval: Misunderstandings and misconceptions at Drug Development Strategies in Oncology, Santa Monica California, October, 2006.
19. Presentation on Innovative Trial Designs in Oncology, Clinical Trials Congress, Las Vegas Nevada, February, 2007.
20. Institute for International Research, Atlanta Georgia, April 2007: Regulatory tradition and the new science: Accelerated Approval, a case study
21. Presentation at DIA, Atlanta, June 2007, "Accelerated approval-15 years later"
22. Presentation at DIA, Atlanta, June 2007: Development of oncology products in US and EU--Can it be better and faster?

23. Invited presentation at PSI (Statisticians in the Pharmaceutical Industry), Royal Statistical Society, London, October 2007: PFS, Historical and Regulatory Considerations.
24. Invited presentation at DIA Progression-Free Survival Workshop in Session on Criteria for Determination of Progression, Bethesda, Md, October 8, 2009.
25. Invited presentation at Society of Clinical Trials Conference: Endpoints, Strength of Evidence, and the FDA Approval Process in Oncology, Baltimore Maryland, May 19, 2009.
26. Presentation at annual DIA meeting: US Regulatory Considerations for Global Oncology Trials, San Diego, June, 2009.
27. Invited speaker: Advanced Biomarker Strategies in Oncology IIR, Boston MA, September 9, 2010.
28. Invited Speaker: Oncology Business Review Webinar: The Big Picture – Forecast 2011, January 2011.
29. Invited Speaker: Molecular Therapeutics of Cancer Research Conference – 2011: Regulatory Considerations in Combining Novel Anticancer Drugs, Monterey, Ca, July 2011.
30. Lecture: Regulatory considerations in Cancer Drug Development, Course in Translating Cancer Discovery into Clinical Practice, NYU Cancer Institute, December 2011.

#### **Selected Publications**

1. Stone A, Bushnell W, Denne J, Sargent D, Amit O, Chen C, Helterbrand J and Williams G. Research outcomes and recommendations for the assessment of progression in cancer clinical trials from a PhRMA working group. Available Online 22 Mar 2011, *Eur J Can*, 2011.
2. Paules M, Casey M, Williams G, Swann S, Murhpy P, Salazar V, Foose D and Baily B. Recommendations for capture, validation and summarization and summarization of data from studies using RECIST of data from studies using RECIST. *Eur J Can*: 47(2011) 697-701.
3. Williams G, Keegan P, Ogden P, Pazdur R, Temple R, McClellan M. FDA's role in the development and approval of drugs, biologics, and devices for cancer. Chapter in: DeVita and Hellman, eds., *CANCER: Principles and Practice of Oncology*, 7th edition. Lippincott Williams & Wilkins, 2005. (Co-author of 8th edition, 2007 and of the 9th edition, 2010)
4. Williams G, Pazdur R. Regulatory Considerations in Clinical Trials of Novel Anticancer Drugs. Chapter in: Adjei and Buolamwini, eds., *Novel Anticancer Agents: Strategies for Discovery and Clinical testing*. Elsevier, Inc. 2006, 263-283.
5. Perez-Gracia JL, Williams G, et al. Assessment of the value of confirming responses in clinical trials in oncology. *Eur J Cancer*. 2005 Jul; 41(11): 1528-32.
6. Williams G. Endpoints for cancer drug approval. *ASCO Educational Book*, 2005.
7. Williams G. Editorial: Cancer drug development: for populations or for individuals? *J Clin Oncol* 2004;22 3441-3442.
8. Williams G, Pazdur R, Temple R. Assessing tumor-related signs and symptoms to support cancer drug approval. *J Biopharm Stat*. 2004 Feb;14(1):5-21.
9. Johnson J, Williams G, Pazdur R. End points and the United States Food and Drug Administration approval of oncology drugs. *J Clin Oncol* 21:1404-1411, 2003.

10. Chiao J, Williams G, Griebel D. A perspective on assessing tumor-related symptoms and health-related quality of life (HRQL) in cancer clinical trials. Book chapter in: Teicher and Andrews, eds., *Anticancer Drug Development Guide: Preclinical Screening, Clinical Trials and Approval*. Humana Press, 2004.
11. Dagher R, Johnson, J, Williams G, Keegan P, Pazdur R. Accelerated Approval of Oncology Products: A Decade of Experience JNCI, Vol. 96, No. 20, October 20, 2004.
12. Williams G, Tun H, Pazdur R, and Chi G. Operational bias in assessing time to progression Time to Progression, Proceedings of ASCO, 2002. 21: Abstract #975.
13. Williams G, Cortazar P, Pazdur R. Developing drugs to decrease the toxicity of chemotherapy. J Clin Oncol. 2001 Jul 15;19(14):3439-41.

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## **SUMMARY**

Biopharma executive with over 20 years of experience in all phases of R&D of large and small molecule therapeutics for cancer and inflammatory diseases. Track record of leadership that delivers rational, coherent and successful programs. Domain area expertise in Translational Sciences (bench to clinic to market). Recognized for strategic and synthetic thinking, communication and accomplishing challenging goals.

## **Professional Experience**

### FoxBiopharma LLC R&D Consultant - present

Large and small molecule oncology therapeutics

- R&D strategy and scientific advice
- Drug candidate search and evaluation for in-licensing
- FDA and EMA briefing documents, filings and meetings

### Amphivena Therapeutics

#### Senior Vice President, R&D – February 2014 - present

- Consultant, R&D for development of a novel biologic TandAb antibody program for hematologic malignancies

### Sunesis Pharmaceuticals

#### Vice President, Development 2008-2013

- Program Leader for vosaroxin (formerly voreloxin, SNS-595)
- Led program from early AML Phase 1 through successful interim analysis of VALOR, a pivotal Phase 3 adaptive design trial
- Translational sciences components of Phase 1b and Phase 2 studies; indication identification for subsequent trials; collaborations/KOL interactions
- EOP2 (CMC and clinical) and EMA Scientific Advice Meetings
- Company representative for Steering Committee and DSMB (open sessions)
- Product & Preclinical Development Head: translational sciences (translational medicine, pharm/tox, ADME), clinical pharmacology, project management, data management, clinical operations and medical writing functions
- Joint Project Team Member for MLN2480 – pan-RAF kinase inhibitor
- Member of executive committee, involved with board interactions, investor, partnering, and in-licensing outreach and diligence

#### Senior Director, Program Leader 2006 – 2008



- Program Leader for vosaroxin in AML and ovarian cancers, and for SNS-032 in B cell malignancies
- Implemented Translational Medicine/Mechanism of Action programs for both projects with in-house research and collaborations with KOLs, MMRC

Chiron Corporation/Novartis 2005-2006

Senior Director, Translational Sciences

- Department Head for Clinical Pharmacology, Preclinical PK, Drug Metabolism and GLP Bioanalytical PK assays and Senior Staff for Translational Sciences
- In addition to oversight of all projects within department, had direct project responsibilities for kinase inhibitors CHIR-265/RAF265, CHIR-258/TKI258/dovitinib and antibodies CHIR-12.12/HCD122, CHIR-RX1; melanoma, AML, MM, other solid tumor and hematologic malignancies

Genencor International, Inc. 2002-2005

R&D Senior Director/Senior Staff Scientist

Co-Leader Research Organization and Head of Pharmacological Sciences

- Built new department responsible for preclinical functions and clinical pharmacology, member of Pharma Management Team responsible for strategic oversight of Healthcare Organization
- Business development scientific liason and support for Healthcare
- Identified in-licensing opportunity for BL22 and CAT-8015 from the Pastan laboratory at NCI currently in development by Medimmune/Astra Zeneca
- Led target ID for immunotoxin and ADEPT platforms

Genentech Inc. 1991-2001

Oncology/Opportunistic Focus Area Leader

Associate Director and Senior Scientist

- Clinical and Experimental Pharmacology/Pharmacokinetics/Metabolism
- Responsible for all oncology projects from late stage research through development stages, as well as several immunology programs
- Cancer Projects: Herceptin; Rituxan; Avastin (anti-VEGF); Apo2 Ligand, anti-CD40; anti-PSCA; Second Generation anti-VEGF; Armed Antibodies
- Anti-HER2 Translational Medicine: Special Studies/Mechanism of Action Program Team Leader for Phase 3 Program. Identified cells mediating Herceptin ADCC leading to new Research focus on antibody effector function
- Co/authored nonclinical and clinical pharmacology sections for Herceptin BLA; company attendee for ODAC
- Immunology & Emerging Opportunities Projects: Xolair (anti-IgE) Raptiva (anti-CD11a), rhuFabV2 for AMD, anti-CD18
- Laboratory resolved mechanism of Xolair:IgE immune complex elimination
- Authored nonclinical Raptiva CTD, nonclinical section for Xolair BLA, pre-IND and IND nonclinical sections for many other programs

### Postdoctoral Research

#### The Rockefeller University

The Laboratory of Medical Biochemistry and The Laboratory of Obesity and Human Behavior (1988-1991)

Advisors: Jules Hirsch, M.D. and Anthony Cerami, Ph.D.

Research: Mechanism of insulin resistance induced by tumor necrosis factor.

The Laboratory of Molecular Parasitology – NIH postdoctoral fellow (1984-1988)

Advisor: George A.M. Cross, Ph.D., F.R.S.

Research: Glycosylphosphatidylinositol-specific phospholipases C from *Trypanosoma brucei* and rat liver plasma membranes.

### Research Associate

#### Tufts New England Medical Center (1978-1980)

Supervisor: Bernard M. Babor, M.D., Ph.D.

Vitamin B<sub>12</sub>-dependent enzymes.

### **Education**

- |      |   |
|------|---|
| 1984 | The Massachusetts Institute of Technology<br>Ph.D. in Mechanistic Enzymology/Biological Chemistry<br>Department of Chemistry 1980-1984<br>Advisor: Christopher T. Walsh |
| 1978 | Bryn Mawr College<br>A.B. Chemistry   |
| 1973 | NSF Pre-college Summer Program 1973<br>The Jackson Laboratories   |

### **Memberships/Appointments**

- The Massachusetts Institute of Technology Chemistry Visiting Committee 2010-present, renewed in 2013 for an additional 4 year term
- AAAS, AACR, ASCO, ASH

### **Post-graduate Training**

- Leadership Development Program, Center for Creative Leadership  
Career Development Coaching
- Pharmacokinetics for the Pharmaceutical Scientist, UCSF
- Physiological Modeling Course; Win-Non Lin Training Course
- GXP training

## Publications

- Graves SW, Fox JA, Babior BM. Deamination of 2-aminopropanol by ethanolamine ammonia-lyase, kinetics and isotope effects for the R and S enantiomers of the substrate. *Biochemistry* 1980;19:3630-3633.
- Jacobson F, Daniels L, Fox JA, Walsh CT, Orme-Johnson WH. Purification and Properties of an 8-hydroxy-5-deazaflavin-reducing Hydrogenase from *Methanobacterium thermoautotrophicum*. *J. Biol. Chem.* 1982;257:3385-3388.
- Kojima N, Fox JA, Hausinger RP, Daniels L, Orme-Johnson WH, Walsh CT. Paramagnetic Centers in the Nickel-containing Deazaflavin-reducing Hydrogenase from *Methanobacterium thermoautotrophicum* *Proc. Nat. Acad. Sci. USA* 1983;80:378-382.
- Lindahl PA, Kojima N, Fox JA, Teo BK, Walsh CT, Orme-Johnson WH. Nickel and Iron EXAFS of F420-reducing Hydrogenase from *Methanobacterium thermoautotrophicum*. *J Am. Chem Soc* 1984;106:362-364.
- Tan S-L, Fox JA, Kojima N, Walsh CT, Orme-Johnson WH. Nickel Coordination in Deazaflavin and Viologen Reducing-Hydrogenase from *Methanobacterium thermoautotrophicum* : Investigation by Electron Spin Echo Spectroscopy. *J Am. Chem Soc* 1984;106:364-366.
- O'Brien RJ, Fox JA, Kopczynski MG, Babior BM. The Mechanism of Action of Ethanolamine Ammonia-lyase, an Adenosylcobalamin-dependent Enzyme. *J. Biol. Chem.* 1985;260:16131-16136.
- Bastion N, Livingston DJ, Jordan L, Fox JA, Orme-Johnson WH, Walsh CT. Hydrogenases of *Methanobacterium thermoautotrophicum*. *Bioinorganic Chemistry of Nickel* 1986, ed. J.Lancaster, VCH Publishers Inc., Deerfield Beach.
- Saltiel AR, Fox JA, Sherline P, Cuatrecasas P. Insulin-Stimulated Hydrolysis of a Novel Glycolipid Generates Modulators of cAMP Phosphodiesterase. *Science* 1986;233:967-972.
- Fox JA, Duszenko M, Ferguson MAJ, Low MG, Cross GAM. Purification and Characterization of a Novel Glycan-Phosphatidylinositol-Specific Phospholipase C from *Trypanosoma brucei*. *J. Biol.Chem.* 1986;261:15767-15771.
- Saltiel AR, Fox JA, Sherline P, Sahyoun N, Cuatrecasas P. Purification of a Phosphatidylinositol Kinase from Bovine Brain Myelin. *Biochem. J.* 1987; 241:759-763.
- Saltiel AR, Sherline P, Fox JA. Insulin-stimulated Diacylglycerol Production Results from Hydrolysis of a Novel Phosphatidylinositol-glycan. *J. Biol. Chem.* 1987;262:1116-1121.

- Fox JA, Livingston DJ, Orme-Johnson WH, Walsh CT. Deazaflavin-reducing Hydrogenase from *Methanobacterium thermoautotrophicum*: I. Purification and Characterization. *Biochemistry* 1987;26:4219-4227.
- Livingston DJ, Fox JA, Orme-Johnson WH, Walsh CT. Deazaflavin-reducing Hydrogenase from *Methanobacterium thermoautotrophicum* : II. Kinetic and Hydrogen Transfer Studies. *Biochemistry* 1987;26:4228-4236.
- Lamont GS, Fox JA, Cross GAM. Glycosyl-sn -12-dimyristylphosphatidylinositol is the Membrane Anchor for *Trypanosoma equiperdum* and *Trypanosoma (Nannomonas) congolense* Variant Surface Glycoproteins. *Mol. Biochem. Parasitology* 1987;24:131-136.
- Fox JA, Soliz NM, Saliel AR. Purification of a Phosphatidylinositol Glycan-Specific Phospholipase C from Rat Liver Plasma Membranes; a Possible Target of Insulin Action. *Proc. Nat. Acad. Sci.* 1987;84:2663-2667.
- Clayton CE and Fox JA. Phosphorylation of Fructose Bisphosphate Aldolase in *Trypanosoma brucei*. *Mol. Biochem. Parasitology* 1989;26:131 - 136.
- Tracy KJ, Morgello S, Koplín B, Fahey TJ III, Fox JA, Aledo A, Manogue KR, Cerami A. The Metabolic Effects of Cachecin/TNF are Modified by Site of Production: Cachecin/TNF-secreting Tumor in Skeletal Muscle Induces Cachexia While Implantation in Brain Produces Predominantly Anorexia. *J. Clin Invest.* 1990;86:2014-2024.
- Nakamura GR, Byrn R, Wilkes DM, Fox JA, Hobbs MR, Hastings R, Wessling HC, Norcross MA, Fendly BM, Berman PW. Strain Specificity and Binding Affinity Requirements of Neutralizing Monoclonal Antibodies to the C4 Domain of gp120 from Human Immunodeficiency Virus Type 1. *J. Virology* 1993;67:6179-6191
- Eigenbrot C, Gonzalez T, Mayeda J, Carter P, Werther W, Hotaling T, Fox JA, Kessler J. X-ray Structures of Fragments from Binding and Non-binding Versions of a Humanized Anti-CD18 Antibody: Structural Indications of the Key Role of  $v_H$  residues 59-65. *Proteins: Structure, Function, and Genetics* 1994;18:49-62.
- Renz ME, Chiu HH, Jones S, Fox J, Kim KJ, Presta LG, Fong S. Structural Requirements for Adhesion of Soluble Recombinant Murine Vascular Cell Adhesion Molecule-1 to Alpha-4-Beta-1. *J. Cell Biol.* 1994;125:1395-1406.
- Werther WW, Gonzalez TN, O'Connor SJ, McCabe S, Hotaling T, Champe M, Fox JA, Jardieu PM, Berman PW, Presta LG. Humanization of an Anti-LFA-1 Monoclonal Antibody and Re-Engineering of the Humanized Antibody for Binding to Rhesus LFA-1. *J. Immunol* 1996;157:4986-4995.
- Fox JA, Hotaling TE, Struble C, Ruppel J, Bates DJ, Schoenhoff MB. Tissue Distribution and Complex Formation with IgE of an Anti-IgE Antibody After

- Intravenous Administration in Cynomolgus Monkeys. *J. Pharmacol. Exp. Ther.* 1996;279: 1000-1008.
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- Sliwkowski MX, Lofgren J, Lewis GD, Hotaling TE, Fendly BM, Fox JA. Nonclinical Studies Addressing the Mechanism of Action of Trastuzumab (Herceptin®). *Seminars in Oncology* 1999;26:60-70.
- Kohne C, Johnson A, Tom S, Peers DH, Gehant RL, Hotaling TA, Brousseau D, Ryll T, Fox JA, Chamow S, Berman PW. Secretion of Glycosylation Site Mutants Can Be Rescued by the Signal/Pro Sequence of Tissue Plasminogen Activator. *J Cellular Biochemistry*;1999:446-461.
- Shields RL, Namenuk K, Hong K, Meng YG, Rae J, Briggs J, Xie D, Stadlen A, Fox JA, Presta LG. High Resolution Mapping of the Binding Site on Human IgG1 for FcγRI, FcγRII, FcγRIII and FcγRn and design of IgG1 variants with improved binding to the FcγR. *J. Biol Chem.* 2001;276:6591-6604.
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- Kelley SK, Harris LA, Xie D, Deforge L, Totpal K, Bussiere J, Fox JA. Pre-clinical Studies to Predict the Disposition of Apo2L/TRAIL in Humans: Characterization of In Vivo Efficacy, Pharmacokinetics and Safety, *J. Pharmacol Exp Ther.* 2001;299:31-8.
- Allison DE, Gourlay SG, Koren E, Fox JA. Pharmacokinetics of rhuMAb CD18, a recombinant humanised monoclonal antibody fragment to CD18, in normal healthy human volunteers. *Biodrugs.* 2002;16:63-70.
- Xiang H, Fox JA, Lowe J, Totpal K, Escandon E. Enhanced tumor killing by Apo2L/TRAIL and CPT-11 co-treatment is associated with p21 cleavage and differential regulation of Apo2L/TRAIL ligand and its receptors, *Oncogene.* 2002;21:3611-3619.
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- Coffey G, Fox JA, Palmieri S, Gonzales M, Bakshi A, Padilla-Eager J, Pippig S, Fielder PJ. Tissue Distribution and Cell-Mediated Clearance of anti-CD11a Antibody in Mice. *Drug Metabolism and Disposition*, 2005;33;623-629.
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- Sarker D, Molife R, Evans TRJ, Hardie M, Marriott C, Butzberger-Zimmerli P Morrison R, Fox JA et al. A Phase I Pharmacokinetic and Pharmacodynamic Study of TKI258, an Oral, Multitargeted Receptor Tyrosine Kinase Inhibitor in Patients with Advanced Solid Tumors. *Clin Cancer Res*. 2008;14; 2075-2081.
- Alderson RF, Kreitman RJ, Chen T, Yeung P, Herbst R, Fox JA, Pastan I. CAT-8015: A Second-Generation Pseudomonas Exotoxin A-Based Immunotherapy Targeting CD22-Expressing Hematologic Malignancies. *Clin Cancer Res*. 2009;15; 832-839.
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- Scatena CD, Kumer JL, Arbitrario JP, Howlett AR, Hawtin RE, Fox, JA, Silverman JA. Voreloxin, a first-in-class anticancer quinolone derivative, acts synergistically with cytarabine in vitro and induces bone marrow aplasia in vivo. *Cancer Chemother Pharmacol*. 2010; 66(5); 881-888.
- Advani RH, Hurwitz HI, Gordon MS, Ebbinghaus SW, Mendelson DS, Wakelee HA, Hoch U, Silverman JA, Havrilla NA, Berman CJ, Fox JA, Allen RS, Adelman DC. Phase 1 experience with voreloxin, a first- in- class anticancer quinolone derivative, in relapsed/refractory solid tumors: a report on two dosing schedules. *Clin Cancer Res*. 2010; 16(7); 2167-2175.
- Tong W-G, Chen R, Plunkett W, Siegel D, Sinha R, Harvey D, Badros AZ, Popplewell L, Coutre S, Fox JA, Mahadocon K, Chen T, Kegley P, Hoch U, Wierda WG. Phase I Study of SNS-032, a Potent and Specific Cdk2, 7 and 9 Inhibitor, in Patients with Advanced Chronic Lymphocytic Leukemia (CLL) and Multiple Myeloma (MM). *J Clin Onc*. 2010; 28(18); 3015-3022.

Hawtin RE, Stockett DE, Byl J, McDowell RS, Tan N, Arkin, MR, Conroy A , Yang W, Osheroff N, Fox JA. Voreloxin is a novel naphthyridine cancer therapeutic that intercalates DNA and poisons topoisomerase II. PLoS One 2010: 5(4): e10186. doi:10.1371/journal.pone.0010186.

Hawtin RE, Stockett DE, Wong OK, Lundin C, Helleday T, Fox JA. Homologous recombination repair is essential for repair of vosaroxin-induced DNA double-strand breaks. Oncotarget 2010: 1; 606-619.

Lancet JE, Ravandi F, Ricklis RM, Cripe LD, Kantarjian HM, Giles FJ, List AF, Chen T, Allen RS, Fox, JA, Michelson GC, Karp JA. A phase 1b study of vosaroxin, an anticancer quinolone derivative, in patients with relapsed or refractory acute leukemia. Leukemia 2011: 12:1801-14.

Stuart RK, Cripe LD, Maris MB, Cooper MA, Stone RM, Shaker RD, Turturro F, Stock W, Mason J, Shami PJ, Strickland SA, Costa LJ, Borthakur G, Michelson GC, Fox JA, Leavitt RD, Ravandi F. REVEAL-1, a phase 2 dose regimen optimization study of vosaroxin in older poor-risk patients with previously untreated AML, submitted 2014.

#### **Published Patents**

(WO/2001/078779) Antibody Alpha4beta7 Integrin And Its Use To Treat Inflammatory Bowel Disease.

(WO/2002/009755) APO-2L Receptor Agonist And CPT-11 Synergism.

(WO/2003/105757) Methods And Compositions For Milieu-Dependent Binding Of A Targeted Agent To A Target.

(WO/2005/058236) CAB Molecules.

(WO/2005/111078) ANTI-CEA scFv-Beta-Lactamase Constructs (CAB Molecules) in ADEPT.

(WO/2006/116076) TAB Molecules.

(WO/2010/099526) Methods Of Using SNS-595 For Treatment Of Cancer Subjects With Reduced BRCA2 Activity.

## **Selected Abstracts and Invited Presentations**

- Pegram MD, Baly D, Wirth C, Gilkerson E, Slamon DJ, Sliwkowski MX., Bauer K, Fox JA. Antibody Dependent Cell-Mediated Cytotoxicity in Breast Cancer Patients in Phase III Clinical Trials of a Humanized Anti-HER2 Antibody. Proceedings American Association for Cancer Research 1997.
- Baly D, Wirth CM, Allison DE, Gilkerson E, Hotaling TE, Fox JA. Development and Characterization of a rhuMAb HER2 Antibody ADCC Assay for Clinical Evaluation of Cytotoxic Potency. Proceedings American Association for Cancer Research 1997;38:A181.
- Fox JA, Reitz B, Hagler K, Hsei V, Keller G, Ryan A, Schoenhoff MB and Widmer R. Pharmacokinetics and Clearance Mechanisms of Anti-IgE:IgE Monoclonal and Polyclonal Complexes. 1997 AAPS National Meeting, Invited Speaker.
- Fox JA. Anti-IgE Antibodies as Therapeutics for Allergic Disease. Advanced Research Seminar at 1998 AAAAI Meeting, Invited Speaker.
- Fox JA. DIA Workshop: "Applications of Pharmacokinetics/Safety Information in Drug Development and Regulatory Decisions" April 26, 2001, Washington, DC, invited speaker.
- Fox, JA. Haas Business School Bioentrepreneur Program. Invited Speaker, Clinical Trials Strategy. 2004.
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**Curriculum Vitae; Michael Foley, Ph.D.;****General Information:**

Michael A. Foley, PhD

**Work:**

Physical: BRB, East 69<sup>th</sup> Street, 16<sup>th</sup> floor  
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 New York, NY 10065  
 Office: 646-962-6126  
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**Home:**

430 East 63<sup>rd</sup> Street, Apt 7J  
 New York, NY 10065  
 212-600-0134

Spouse: Jennifer Foley  
 Daughter: Katharine Foley

Citizenship: United States of America

Date of birth: March 1, 1962

**Education:**

INSTITUTION AND LOCATION	DEGREE (if applicable)	YEAR	FIELD OF STUDY
St. Norbert College; Green Bay, WI	B.S.	1984	Chemistry
Utah State University; Logan, UT	M.S.	1986	Chemistry
Harvard University; Cambridge, MA	Ph.D.	1999	Chemistry

**PROFESSIONAL EXPERIENCE**

**Tri-Institutional Therapeutics Discovery Institute, New York, NY** **2014- present**

Sanders Director of the Tri-Institutional Therapeutics Discovery Institute and the Sanders Innovation and Education Initiative

**KDAC Therapeutics Inc. Founding Board member** **2013- present**

**Broad Institute, Chemical Biology Platform, Cambridge, MA** **2006 – 2013**

Director, Chemical Biology Platform, Center for the Science of Therapeutics, Management Committee Member

**Forma Therapeutics, Co-founder, Board Member** **2007 – present**

**Co-founder and Vice President of Chemistry, Infinity Pharmaceuticals** **2001-2006**

**Co-Founder, Board Member and Consultant, CombinatoRx, Inc** **2001-2009**

**Co-Founder, Harvard Institute of Chemistry and Cell Biology,  
Faculty appointment in Cell Biology**

**1999-2001**

**Chemist, Glaxo Wellcome, RTP, NC**

**1990 – 1999**

**Research Chemist, Bristol-Myers Squibb, Wallingford, CT**

**1987 – 1990**

**Peer Reviewed Publications:**

Over, Björn; McCarren, Patrick; Artursson, Per; **Foley, Michael**; Giordanetto, Fabrizio; Grönberg, Gunnar; Hilgendorf, Constanze; Lee, Maurice; Matsson, Pär; Muncipinto, Giovanni; Pellisson, Melanie; Perry, Matthew; Svensson, Richard; Duvall, Jeremy; Kihlberg, Jan. Impact of Stereospecific Intramolecular Hydrogen-Bonding on Cell Permeability. *J. Med. Chem.* **Submitted** January 12, **2014**

Jason T. Lowe, Maurice D. Lee, IV, Lakshmi B. Akella, Emeline Davoine, Etienne J. Donckele, Landon Durak, Jeremy R. Duvall, Baudouin Gerard, Edward B. Holson, Adrien Joliton, Sarathy Kesavan, Berenice C. Lemercier, Haibo Liu, Jean-Charles Marié, Carol A. Mulrooney, Giovanni Muncipinto, Morgan Welzel-O'Shea, Laura M. Panko, Ann Rowley, Byung-Chul Suh, Meryl Thomas, Florence F. Wagner, Jingqiang Wei, **Michael A. Foley**, and Lisa A. Marcaurelle . [Synthesis and Profiling of a Diverse Collection of Azetidine-Based Scaffolds for the Development of CNS-Focused Lead-like Libraries](#). *J. Org. Chem.*, **2012**, 77 (17), pp 7187–7211

Chris Dockendorff, Marek M. Nagiec, Michel Weïwer, Sara Buhrlage, Amal Ting, Partha P. Nag, Andrew Germain, Han-Je Kim, Willmen Youngsaye, Christina Scherer, Melissa Bennion, Linlong Xue, Benjamin Z. Stanton, Timothy A. Lewis, Lawrence MacPherson, Michelle Palmer, **Michael A. Foley**, José R. Perez, and Stuart L. Schreiber. [Macrocyclic Hedgehog Pathway Inhibitors: Optimization of Cellular Activity and Mode of Action Studies](#). *ACS Med. Chem. Lett.*, **2012**, 3 (10), pp 808–813

Richard W. Heidebrecht, Jr., Carol Mulrooney, Christopher P. Austin, Robert H. Barker, Jr., Jennifer A. Beaudoin, Ken Chih-Chien Cheng, Eamon Comer, Sivaraman Dandapani, Justin Dick, Jeremy R. Duvall, Eric H. Eklund, David A. Fidock, Mark E. Fitzgerald, **Michael A. Foley**, Rajarshi Guha, Paul Hinkson, Martin Kramer, Amanda K. Lukens, Daniela Masi, Lisa A. Marcaurelle, Xin-Zhuan Su, Craig J. Thomas, Michel Weïwer, Roger C. Wiegand, Dyann Wirth, Menghang Xia, Jing Yuan, Jinghua Zhao, Michelle Palmer, Benito Munoz, and Stuart Schreiber. [Diversity-Oriented Synthesis Yields a Novel Lead for the Treatment of Malaria](#). *ACS Med. Chem. Lett.*, **2012**, 3 (2), pp 112–117

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S.J., Palmer, M., **Foley, M.A.** An Aldol-Based Build/Couple/Pair Strategy for the Synthesis of medium- and Large-Sized Rings: Discovery of Macrocyclic Histone Deacetylase Inhibitors. *J. AM. Chem. Soc.* **2010**, 132, 16962-16976.

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Helen E. Blackwell, Lucy Perez, Robert Stavenger, John Tallarico, Elaine Cope-Eatough, **Michael A. Foley** Stuart L. Schreiber A One-Bead, One-Stock Solution Approach to Chemical Genetics: Part 1. *Journal of the American Chemical Society Chemistry and Biology*, 8, 2001, 1167-1183.

John A. Tallarico, Kris M. Depew, Nick J. Westwood, Henry E. Pelish, Craig W. Lindsley, Matthew D. Shair, Stuart L. Schreiber and **Michael A. Foley**. An Alkylsilyl-Tethered, High Capacity Solid Support Amenable to One Compound - One Encoded Bead Diversity Oriented Synthesis. *Journal of Combinatorial Chemistry*, 3, 2001, 312-318.

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Poindexter, G. S.; **Foley, M. A.**; Macdonald, J. E.; Sarmiento, J. G.; Bryson, C.; Goggins, G. D.; Cavanagh, R. L.; Buyniski, J. P. Isosteric Replacement in a Series of Beta-Substituted Monophosphonate Calcium-Antagonists. Bioorganic & Medicinal Chemistry Letters 1993, 3, 2817-2820.

Poindexter, G. S.; **Foley, M. A.**; Licause, J. F. Metalation of 1,4-Dihydropyridine Esters. Tetrahedron Letters 1989, 30, 3393-3396.

Poindexter, G. S.; **Foley, M. A.**; Licause, J. F. Metalation of Hantzsch Dihydropyridines. Abstracts of Papers of the American Chemical Society 1988, 196, 334-ORGN.

**Foley, M. A.**; Hassman, A. S.; Drewry, D. H.; Greer, D. G.; Wagner, C. D.; Feldman, P. L.; Bennan, J.; Bickett, D. M.; McGeehan, G. M.; Lambert, M. H.; Green, M. Rapid synthesis of novel dipeptide inhibitors of human collagenase and gelatinase using solid phase chemistry. Bioorganic & Medicinal Chemistry Letters 1996, 6, 1905-1910.

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Brown, J. D.; **Foley, M. A.**; Comins, D. L. A Highly Stereocontrolled, 4-Step Synthesis of (+/-)-Lasubine- II. Journal of the American Chemical Society 1988, 110, 7445

**Non-Peer Reviewed Publications:**

St. Norbert College Magazine, March 27, 2013. <http://www.snc.edu/magazine/2013spring/foley.html>

**Patents:**

US8349832B2

COMPOUNDS AND COMPOSITIONS FOR TREATING CANCER

Inventors: Michael Andrew Foley, Chestnut Hill, MA (US); Robert Gould, Beverly, MA (US); Peter Elliott, Marlboro, MA (US); Anna Mandinova, Newton, MA (U S)

US8318737B2

COMPOUNDS AND COMPOSITIONS FOR TREATING CANCER

Inventors: Michael Andrew Foley, Chestnut Hill, MA (US); Robert Gould, Beverly, MA (US); Peter Elliott, Marlboro, MA (US); Anna Mandinova, Newton, MA (US); Sam Lee, Newton, MA (US)

US8236956B2

CYCLOPAMINE ANALOGUES AND METHODS OF USE THEREOF

Inventors: Julian Adams, Boston, MA (US); Alfredo C. Castro, Winchester, MA (US); Michael A. Foley, Chestnut Hill, MA (US); Somarajan Nair, Belmont, MA (US); Marta Nevalain, Quincy MA (US); James Porter Brighton, MA (US); Martin Tremblay, Melrose, MA (US)

US8080553B2

METHODS AND REAGENTS FOR THE TREATMENT OF IMMUNOINFLAMMATORY DISORDERS

Inventors: Curtis Keith, Boston, MA (US); Alexis Borisy, Arlington, MA (US); Grant R. Zimmermann, Somerville, MA (US); Edward Roydon Jost-Price, West Roxbury, MA (US); Palaniyandi Manivasakam, West Roxbury, MA (US); Nicole Hurst, Boston, MA (US); Michael A. Foley, Chestnut Hill, MA (US); Michael S. Slavonic, Quincy, MA (US); Brendan Smith, Somerville, MA (US); Benjamin A. Auspitz, Cambridge, MA(US)

US7915265B2

COMBINATIONS FOR THE TREATMENT OF IMMUNOINFLAMMATORY DISORDERS

Inventors: Curtis Keith, Boston, MA (US); Alexis Borisy, Arlington, MA (US); Grant Zimmermann, Somerville, MA (US); Edward Roydon Jost-Price, West Roxbury, MA (US); Palaniyandi Manivasakam, West Roxbury, MA (US); Nicole W. Hurst, Boston, MA (US); Michael A. Foley, Chestnut Hill, MA(US)

US7875628B2

CYCLOPAMINE ANALOGUES AND METHODS OF USE THEREOF

Inventors: Julian Adams, Boston, MA (US); Alfredo C. Castro, Winchester, MA (US); Michael A. Foley, Chestnut Hill, MA (US); Somarajannair Janardanannair, Woburn, MA (US); Marta Nevalainen, Quincy, MA (US); James R. Porter, Rowley, MA (US); Martin R. Tremblay, Melrose, MA (US)

US7851637B2

COMPOUNDS AND METHODS FOR INHIBITING THE INTERACTION OF BCL PROTEINS WITH BINDING PARTNERS

Inventors: Alfredo C. Castro, Winchester, MA (US); Wei Deng, Lexington, MA (US); Kristopher M. Depew, Acton, MA (US); Michael A. Foley, Chestnut Hill, MA (US); Christian C. Fritz, Natick, MA (US); Asimina T. Georges Evangelinos, Andover, MA (US); Michael J. Grogan, Arlington, MA (US); Nafeeza Hafeez, West Roxbury, MA (US); Edward B. Bolson, Newton Highlands, MA (US); Brian T. Hopkins, Brookline, MA (US); Nii O. Koney, Somerville, MA (US); Tao Liu, Ashland, MA (US); David A. Mann, Swampscott, MA (US); Lisa A. Marcaurette, Arlington, MA (US); Daniel A. Snyder, Cambridge, MA (US); Dennis J. Underwood, Jamaica Plain, MA (US); Andrew A. Wylie, Brookline, MA (US); Lin-Chen Yu, Wollaston, MA (US); Lin ping Zhang, Lexington, MA (US)

US7407967B2

CYCLOPAMINE ANALOGUES AND METHODS OF USE THEREOF

Inventors: Julian Adams, Boston, MA (US); Alfredo C. Castro, Winchester, MA (US); Michael A. Foley, Chestnut Hill, MA (US); Somarajan Nair Janardanan Nair, Belmont, MA (US); Marta Nevalainen, Quincy, MA (US); James R. Porter, Brighton, MA (US); Martin R. Tremblay, Melrose, MA (US)

US7253155B2

COMBINATIONS FOR THE TREATMENT OF IMMUNOINFLAMMATORY DISORDERS

Inventors: Curtis Keith, Boston, MA (US); Alexis Borisy, Boston, MA (US); Grant Zimmerman, Somerville, MA (US); Edward Roydon J ost-Price, West Roxbury, MA (US); Palaniyandi Manivasakam, Brighton, MA (US); Nicole Hurst, Boston, MA (US); Michael A. Foley, Chestnut Hill, MA (US)

US7230004B2

CYCLOPAMINE ANALOGUES AND METHODS OF USE THEREOF

Inventors: Julian Adams, Boston, MA (US); Alfredo C. Castro, Winchester, MA (US); Michael A. Foley, Chestnut Hill, MA (US); Somarajan Nair Janardanan Nair, Belmont, MA (US); Marta Nevalainen, Quincy, MA (US); James R. Porter, Brighton, MA (US); Martin R. Tremblay, Melrose, MA (US)

US7148216B2

COMBINATIONS OF DRUGS FOR THE TREATMENT OF NEOPLASTIC DISORDERS

Inventors: Alexis Borisy, Boston, MA (US); Curtis Keith, Boston, MA (US); Michael A. Foley, Chestnut Hill, MA (US); Brent R. Stockwell, Boston, MA (US)

US7109377B2

SYNTHESIS OF COMBINATORIAL LIBRARIES OF COMPOUNDS REMINISCENT OF NATURAL PRODUCTS

Inventors: Stuart L. Schreiber, Boston, MA (US); Matthew D. Shair, Somerville, MA (US); Derek S. Tan, Rochester, NY (US); Michael A. Foley, Somerville, MA (US); Brent R. Stockwell, Boston, MA (US)

US6846816B2

COMBINATIONS OF DRUGS FOR THE TREATMENT OF NEOPLASTIC DISORDERS

Inventors: Alexis Borisy, Boston, MA (US); Curtis Keith, Boston, MA (US); Michael A. Foley, Chestnut Hill, MA (US); Brent R. Stockwell, Boston, MA (US)

US6693125B2

COMBINATIONS OF DRUGS (E.G., A BENZIMIDAZOLE AND PENTAMIDINE)  
FOR THE TREATMENT OF NEOPLASTIC DISORDERS

Inventors: Alexis Borisy, Boston, MA (US); Curtis Keith, Boston, MA (US); Michael A. Foley, Chestnut Hill, MA (US); Brent R. Stockwell, Boston, MA (US)

US6569853B1

COMBINATIONS OF CHLORPROMAZINE AND PENTAMIDINE FOR THE TREATMENT OF  
NEOPLASTIC DISORDERS

Inventors: Alexis Borisy, Boston, MA (US); Curtis Keith, Boston, MA (US); Michael A. Foley, Chestnut Hill, MA (US); Brent R. Stockwell, Boston, MA (US)

US6448443B1

SYNTHESIS OF COMBINATORIAL LIBRARIES OF COMPOUNDS REMINISCENT OF  
NATURAL PRODUCTS

Inventors: Stuart L. Schreiber, Boston; Matthew D. Shair, Somerville, both of MA (US); Derek S. Tan, Rochester, NY (US); Michael A. Foley, Somerville; Brent R. Stockwell, Boston, both of MA (US)

US5252560

CYCLIC IMIDE DERIVATIVES, COMPOSITIONS AND USE

Inventors: Peter L. Myers, Chapel Hill; Andrew B. McElroy, Durham, both of N.C.; Michael Gregson, Greenford, Great Britain; Peter J. Brown, Chapel Hill, N.C.; Howard G. Davies, Greenford, Great Britain; David H. Drewry, Durham; Michael A. Foley, Chapel Hill, both of N.C.





# CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

Oversight Committee Nominations Subcommittee

Peer Review Panel Nominations

Prevention

# Michael Holtz, APR

Award-winning communications professional with 17 years of experience in media advocacy, federal and grassroots issues management, and public relations.

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4557 Twin Pines Drive | Knoxville, TN 37921 | michael\_a\_holtz@yahoo.com | mobile: 865.414.3191

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## Summary of Qualifications

- Seventeen years of public and government relations experience, including 12 years in the non-profit sector, and five years in the health care sector.
- Develop relationships and network with internal and external publics to expand contacts, cultivate relationships, and meet organizational goals and objectives.
- Deploy successful grassroots and media campaigns using traditional and social media tactics.

---

## Professional Experience

ASSOCIATE DIRECTOR, MEDIA ADVOCACY – SOUTH REGION | American Cancer Society Cancer Action Network, Inc. | January 2013 – Present | Knoxville, Tenn.

- Provide strategic support and counsel for state legislative initiatives in fourteen-state
- Lead successful media campaigns on a wide array of federal and state issues, including research and cancer screening program funding, smoke-free workplace laws, tobacco tax increases, and health care reform.
- Work with government relations directors, grassroots staff and volunteers to create tactics that put pressure on elected officials.
- Train volunteers and staff to deliver messages to a variety of publics, including legislators, the media, the general public and other advocates.
- Served as Mid-South Division Media Advocacy Director from March 2008-December 2013 before being promoted; and Media Advocacy Specialist from December 2006 to March 2008 before being promoted.

COMMUNICATIONS & MARKETING SPECIALIST | American Cancer Society | July 2002 – December 2006 | Knoxville, Tenn.

- Provided marketing and communications support to four East Tennessee offices.
- Worked directly with contacts at newspapers, television stations and radio stations to promote organizational initiatives and fund-raising events.
- Trained volunteers to be media spokespersons, and led staff and volunteer trainings to help answer difficult questions about the organization.

MARKETING & PUBLIC RELATIONS SPECIALIST | St. Mary's Health System | September 1998 – July 2002 | Knoxville, Tenn.

- Developed and managed aggressive earned media program and maintained positive relationships with news media to obtain publicity for the health system.
- Produced collateral materials, including the annual physicians directory, monthly newsletter, brochures, newspaper ads and internal videos.
- Served as the health system Public Information Officer.

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## Education and Training

- Accredited in Public Relations | Public Relations Society of America | August 2009
- M.S. Communications | University of Tennessee | December 1998
- B.A. Mass Communication | University of Wisconsin-Milwaukee | May 1992

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## Recognition

- Grassroots Advocacy Professional of the Year | American Cancer Society Cancer Action Network, Inc. | 2012
- Award of Excellence for Non-Profit Government Relations Campaign | Volunteer Chapter PRSA | Federal Research Funding Support Campaign | 2012
- Award of Excellence for Non-Profit Government Relations Campaign | Volunteer Chapter PRSA | Alabama Breast and Cervical Cancer Early Detection Program Funding Crisis | 2011
- Inaugural Make Your Mark Award | American Cancer Society Mid-South Division, Inc. | 2005
- Associate Commendation of Excellence Award | American Cancer Society Mid-South Division, Inc. | 2005
- Sixteen additional professional recognition and community service awards.

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## Community Service

- President-Elect | Volunteer Chapter PRSA | January 2013
- Coach | Leukemia and Lymphoma Society Team in Training Program | 2012-13
- Social Media Chair | Covenant Health Knoxville Marathon | 2012-13
- Chair | Volunteer Chapter PRSA Annual “V” Awards Gala | April 2013
- Presenter | “How to Make Facebook Work for Non-Profit Organizations” | Social Media Jam presented by the Knox County Health Department | January 2013
- Presenter | “Government Detailing and the Impact on Colon Cancer Screening” | Colon Cancer Alliance | December 2012
- Ethics Chair | Volunteer Chapter PRSA Board of Directors | 2011
- Presenter | “Media Advocacy Training and Best Practices” | American Cancer Society Cancer Action Network Advocacy Leadership Summit and Lobby Day | 2009 and 2010
- Presenter | “Earned Media Best Practices” | National Highway Transportation and Safety Administration Annual Marketing Forum | 2007
- Auction Chair/Cast Member | ETSPJ Annual Front Page Follies | 2006 and 2007
- President | East Tennessee Chapter JRDF Board of Directors | 2000 – 2002
- Public Relations Chair | East Tennessee Chapter JRDF | 1998 – 2000
- President | Farragut-West Knox Chamber of Commerce Board of Directors | 1999 – 2000

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## Filmography

- *The Next* | Winner, Audience Choice Award for Short Film | Knoxville Horror Film Festival | 2010

# *Curriculum Vitae*

**MARCUS PLESCIA MD, MPH**

January 21, 2014

## **PERSONAL INFORMATION**

Mecklenburg County Health Department  
249 Billingsley Road  
Charlotte, NC 28211  
(704) 336 2299  
Marcus.Plescia@mecklenburgcountync.gov

Born: November 19, 1962. Tallahassee, Florida  
Married: Ruth Ann Grissom  
Home Address: 189 Westminster Dr. NE,  
Atlanta, GA 30309  
(919) 740-2618 cell  
(404) 872-0602 home  
marcusplescia@bellsouth.net

## **EDUCATION AND TRAINING**

University of North Carolina at Chapel Hill  
**Fellowship in Academic Family Medicine** 1996-1997

Montefiore Medical Center, Bronx, NY  
**Residency Program in Social Medicine:** Family Practice 1990-1993

University of North Carolina at Chapel Hill  
**Doctor of Medicine** May 1990  
**Master of Public Health** August 1989  
**Bachelor of Science in Biology** May 1984

## EMPLOYMENT HISTORY

Mecklenburg County Health Department

**Director**

February 2014-present

- Lead a metropolitan health department with 500 employees and a budget of \$50 million
- Oversee core activities in environmental health, school health, community services and clinical services
- Oversee the collection and monitoring of all community vital statistics
- Serve as health policy advisor to the board of county commissioners
- Oversee state contract to provide NBCCEDP services
- Represent the county with the NC Division of Public Health
- Serve as primary liaison to the local health care system

Centers for Disease Control and Prevention, Atlanta GA

**Director**, Division of Cancer Prevention and Control

July 2009-present.

- Lead a national program with 185 employees and a \$330 million budget.
- Directed all scientific, policy, and programmatic issues related to four national grant programs provided to US states, tribes and territories to promote cancer screening, provide cancer screening services, operate state cancer registries and support state cancer planning efforts.
- Led a program of cancer research focused on surveillance and health services research.
- Oversaw the National Program of Cancer Registries which compiles surveillance data on cancer incidence and publishes US cancer statistics annually.
- Directed the use of federal appropriations to develop public health interventions for prostate, skin and gynecologic cancers.
- Coordinated activities of two federal advisory committees on breast cancer.
- Served as primary liaison for the Centers for Disease Control to the National Cancer Institute and the American Cancer Society.
- Provided periodic patient care in Indian Health Service facilities.

## **EMPLOYMENT HISTORY (Continued)**

North Carolina Division of Public Health, Raleigh NC

**Chief, Chronic Disease and Injury Section**

November 2003-July 2009

- Led a state program which includes 150 employees and a \$30 million budget.
- Directed the program planning, policy and evaluation efforts for nine state and federally funded public health programs and the State Center for Health Statistics.
- Served on the senior leadership team for the NC Division of Public Health.
- Provided oversight for the state Advisory Committee for Cancer Control, NC cancer registry, state cancer assistance program and the NC Breast and Cervical Cancer Screening program
- Coordinated activities of three legislative task forces and served as policy advisor to appointed members.
- Provided technical assistance and guidance to state agencies and local health departments on chronic disease prevention and control.
- Served as Division liaison to the North Carolina Medical Society, NC Academy of Family Medicine and Blue Cross Blue Shield of NC.
- Provided patient care in local health department facilities.

Carolinas Medical Center Department of Family Medicine, Charlotte NC

**Assistant Residency Director**

September 1998-November 2003

**Principal Investigator, CDC REACH 2010**

October 1999-November 2003

Carolinas Healthcare System

**Alternate Medical Director for Mecklenburg County**

September 1997-November 2003

- Developed and led the CDC Racial and Ethnic Approaches to Community Health (REACH 2010) grant in Charlotte NC, a \$7 million community demonstration project to improve health disparities in an African American community.
- Started and managed a satellite residency training program which includes six family medicine residents in an eight physician community health center serving an urban underserved community.
- Served as medical consultant for a \$3.3 million HRSA-funded regional, community health assessment project.
- Developed and supervised a cervical cancer diagnostic clinic (colposcopy) at Mecklenburg County Health Department.
- Provided primary medical care to medically underserved patients in hospital, health department and primary care settings.
- Periodically assisted Mecklenburg County Health Department. Served as a media contact, supervised health department clinicians, advised the Health Director, supported infectious disease nurses and attended meetings of the epidemiology and regional surveillance teams.

## **EMPLOYMENT HISTORY (Continued)**

Montefiore Medical Center Department of Family Medicine, Bronx NY

### **Medical Director, Care for the Homeless Team**

July 1993-July 1995

- Supervised a medical team of three nurse practitioners providing clinical care in diverse community settings in New York City.
- Provided primary medical care in a hospital and community health center setting.
- Served as medical student rotation coordinator at a community health center.

## ACADEMIC APPOINTMENTS

University of North Carolina School of Medicine, Chapel Hill, NC  
Adjunct Associate Professor 2004-present  
Clinical Associate Professor 2003  
Clinical Assistant Professor 1995-2002

## CREDENTIALS/LICENSURE

Diplomate: American Board of Family Practice, 1993.  
Recertification: 1999, 2005  
Medical License: NC 95-01062 (1995-present), NY 188880 (1992-1995)

## HONORS, AWARDS AND FELLOWSHIPS

**Eugene Meyer Traveling AHEC Fellowship**, NC AHEC  
Awarded to study General Practice/Public Health partnerships in the National Health Service  
September 2000. \$3000

**David Citron Award** UNC statewide Department of Family Medicine, 2000  
Outstanding Junior Faculty in Family Medicine in North Carolina.

**Family Practice Directors Award** Montefiore Medical Center, 1995  
Junior Faculty of Distinction.

**Cecil Sheps Award in Social Medicine** UNC School of Medicine, 1990  
Awarded to the member of each class who demonstrates outstanding scholarship and commitment in the field of social medicine.

**Delta Omega** National Public Health Honor Society, 1989

**International Fellowship** UNC Department of Social Medicine  
Awarded to study community oriented primary care in Kenya, 1988. \$2000.  
Awarded to study primary care in Great Britain, 1986. \$1200.

**Phi Beta Kappa**, 1984



## **PROFESSIONAL SERVICE**

### **Professional Societies and Appointments**

C-Change 2009-present

Mission, Strategy and Implementation Committee, 2010-present

Prevention and Early Detection Subcommittee, 2009-present

National Institute of Environmental Health Sciences

Federal Advisory Committee on Breast Cancer and the Environment

2010-2012

North Carolina Institute of Medicine 2008-present

National Association of Chronic Disease Directors. 2003-2009

President 2008

Board of Directors, 2006-2009

Co-Chair Policy Committee, 2006-2009

North Carolina Medical Society. 1996-2010

Board of Directors, 2008-2009

Leadership Academy, 2005-2006

Family and Public Health Committee, 2003-2009

Chair 2006-2008

American Academy of Family Physicians. 1992-present

NC Chapter, Government Relations Committee 2006-2009

Society of Teachers in Family Medicine. 1996-2003

Group on Community Medicine. 1995-2003

American Public Health Association. 1991-present

### **Manuscript Reviewer**

Preventing Chronic Disease

American Journal of Public Health

Journal of Family Practice

## **GRANTS FUNDED**

### **Centers for Disease Control and Prevention**

Cooperative Agreements to support multiple chronic disease categorical programs in the North Carolina Division of Public Health, Chronic Disease and Injury Section  
Annual funding ~\$15,000,000.

### **Centers for Disease Control and Prevention**

Principal Investigator: Racial and Ethnic Approaches to Community Health 2010, Implementation Project. "Community Mobilization for Cardiovascular Health."  
October 2000-September 2007. \$6,896,000. 40%FTE: 2000-2003

### **Charlotte-Mecklenburg Health Services Foundation, Inc.**

Funding for third year resident project to implement and evaluate a Church-based nutrition intervention in the Northwest Corridor community. 2001. \$16,585.

### **Centers for Disease Control and Prevention**

Principal Investigator: Racial and Ethnic Approaches to Community Health 2010, Demonstration Project. "Community Mobilization for Cardiovascular Health."  
October 1999-September 2000. \$243,889. 40%FTE.

### **Health Resources and Services Administration.**

Consultant: Carolinas Community Health Institute  
Funded through the Rural Health Outreach Program  
September 1998-October 2004. 3,310,000. 10% FTE

### **Charlotte-Mecklenburg Health Services Foundation, Inc.**

Funding for third year resident project to implement and evaluate community walking clubs in the Northwest Corridor communities. 1998. \$10,503.

### **Charlotte-Mecklenburg Health Services Foundation, Inc.**

Funding for a community assessment survey for the Northwest Corridor Community-Oriented Primary Care project. 1997. \$14,832.

## PUBLICATIONS

### *Peer Reviewed*

Henley SJ, Roland K, Grossman M, White M, Plescia M. Opportunities to prevent cancer by reducing alcohol use among U.S. adults. In Review: Preventing Chronic Disease.

Guy G, Richardson L, Pignone M, Plescia M. Costs and Benefits of an Organized FIT-based Colorectal Cancer Screening Program in the United States. In Press: Cancer

Plescia M, Henley J, Pate A, Underwood JM, Rhodes K. Lung cancer deaths among American Indians and Alaska Natives, 1999-2009. In Press: American Journal of Public Health.

Espy D, Jim M, Cobb N, Bartholomew M, Becker T, Haverkamp D, Plescia M. Leading causes of death and all-cause mortality in American Indians and Alaska Natives. In Press: American Journal of Public Health.

Plescia M, White M. The National Prevention Strategy: Applying Scientific Evidence to Expand Mammography Utilization. American Journal of Public Health. 2013;103(9):1545-1548.

Seeff LC, DeGross A, Joseph DA, Royalty J, Tangka FKL, Nadel M, Plescia M. Moving Forward: Using the Experience of CDCs' Colorectal Cancer Screening Demonstration Program to Guide Future Colorectal Cancer Programming Efforts. Cancer. 2013;119(15):2940-2946.

Wilkes M, Srinivasan M, Cole G, Tardif R, Richardson LC, Plescia M. Discussing Uncertainty and Risk in Primary Care: Recommendations of a Multi-Disciplinary Panel Regarding Communication Around Prostate Cancer Screening. J Gen Intern Med. 2013; DOI: 10.1007/s11606-013-2419-z

Donahue KE, Newton WP, Lefabvre A, Plescia M. The Natural History of Practice Transformation: Development and Initial Testing of an Outcomes Based Model. Annals of Family Medicine. 2013;11(3):212-219.

Eheman C, Henley SJ, Ballard-Barbash R, Jacobs EJ, Schymura MJ, Noone A, Pan L, Anderson RN, Fulton JE, Kohler BA, Jemal A, Ward E, Plescia M, Ries LAG, Edwards BK. Annual Report to the Nation on the Status of Cancer, 1975-2008, Featuring Cancers Associated With Excess Weight and Lack of Sufficient Physical Activity. Cancer. 2012 118(9):2338-66.

Plescia M, Wansink D, Waters HR, Malek S. Medical Costs of Second Hand Smoke Exposure in North Carolina. North Carolina Medical Journal. 2011;72(1);7-12.

***Peer Reviewed Publications (continued)***

Downie DL, Schmid D, Plescia M. Do Treatment Differences Explain Racial Disparities in Blood Pressure Control? Analysis of a Medicaid Population. *Preventing Chronic Disease*. 2011;8(3). [http://www.cdc.gov/pcd/issues/may/10\\_0070.htm](http://www.cdc.gov/pcd/issues/may/10_0070.htm).

Young S, Halladay J, Plescia M. Personnel Policy Creates Support for State Employee Worksite Wellness Programs in North Carolina. *Preventing Chronic Disease*. 2011;8(2); [http://www.cdc.gov/pcd/issues/2011/mar/10\\_0069.htm](http://www.cdc.gov/pcd/issues/2011/mar/10_0069.htm)

Henley SJ, King JB, German RR, Richardson LC, Plescia M. Surveillance of Screening-Detected Cancers-United States, 2004-2006. *MMWR Surveillance Summary*. November 26, 2010;59(SS-9):1-25

Donahue K, Plescia M. Clinical Inquiry: Do standing orders improve outcomes for chronic disease control in ambulatory practice? *Journal of Family Practice*. 2010;59(4):226-227.

Porterfield DS, Reaves J, Konrad TR, Weiner BJ, Garrett JM, Davis M, Dickson CW, Plescia M. Assessing local health department performance in diabetes prevention and control-North Carolina, 2005. *Preventing Chronic Disease* 2009;6(3). [http://www.cdc.gov/pcd/issues/2009/jul/08\\_0130.htm](http://www.cdc.gov/pcd/issues/2009/jul/08_0130.htm).

Plescia M, Groblewski M, Chavis L. A Lay Health Advisor Program to Promote Community Capacity and Change. *Health Promotion Practice*. 2008;9(4):434-439.

Plescia M, Herrick H, Chavis L. Health Behavior Changes in an African American Community: The Charlotte Racial and Ethnic Approaches to Community Health Project. *American Journal of Public Health*. 2008;98(9):1678-1685.

Buescher PA, Whitmire JT, Plescia M. Relationship between body mass index and medical care expenditures for North Carolina adolescents enrolled in Medicaid in 2004. *Preventing Chronic Disease*. 2008;5(1). [http://www.cdc.gov/pcd/issues/2008/jan/06\\_0131.htm](http://www.cdc.gov/pcd/issues/2008/jan/06_0131.htm).

Scheid TL, Joyner DR, Plescia M, Steps to a Negotiated Consensus: A Framework for Developing Community Health Initiatives. *Research in the Sociology of Health Care*. 2006;24:235-257.

DeBate RD; Plescia M. I could live other places, but this is where I want to be: Support for natural helper initiatives. *International Quarterly of Community Health Education*, 2005;23(4):343-355.

***Peer Reviewed Publications (continued)***

Plescia M; Young S; Ritzman R. Statewide Community-Based Health Promotion: A North Carolina Model to Build Local Capacity for Chronic Disease Prevention. Preventing Chronic Disease [serial online] October 2005. [http://www.cdc.gov/pcd/issues/2005/oct/05\\_0020.htm](http://www.cdc.gov/pcd/issues/2005/oct/05_0020.htm).

Plescia M; Malek S; Shopland D et al. Protecting Workers from Secondhand Smoke in North Carolina. North Carolina Medical Journal. North Carolina Medical Journal May/June 2005;66(3):186-191.

Plescia M, Leach L, Meriwether R. Clinical Inquiry. What are the Medical Contraindications to vaccination? Journal of Family Practice. 2005 Jul; 54(7):621-3.

Coeytaux, R; Gillespie, H; Callahan, L; Kaufman, J; Plescia, M; Williams, C; Sloane, P. Racial Disparities in Health between White and African American Family Practice Patients: Clinical Implications. NC Medical Journal. November/December 2004;65(6):330-334.

Plescia, M; Scheid T; Joyner D. A Regional Health Care System Partnership with Local Communities to Impact Chronic Disease. Preventing Chronic Disease [serial online] October 2004. [http://www.cdc.gov/pcd/issues/2004/oct/04\\_0020.htm](http://www.cdc.gov/pcd/issues/2004/oct/04_0020.htm).

Plescia M, Joyner DR, Scheid TL. A regional health care system partnership with local communities to impact chronic disease. Preventing Chronic Disease (serial online) October 2004. [http://www.cdc.gov/pcd/issues/2004/oct/04\\_0020.htm](http://www.cdc.gov/pcd/issues/2004/oct/04_0020.htm).

Debate, R; Plescia, M; Joyner D; Spann, LP. A Qualitative Assessment of Charlotte REACH: An Ecological Perspective for Decreasing CVD and Diabetes Among African-Americans. Ethnicity and Disease. Summer 2004;14(3S1):77-82.

Plescia M and Leach L. Clinical Inquiry. Should Varicella Vaccine be Given to all Children? Journal of Family Practice. June 2004; 53(6):271-273.

Plescia. M; Groblewski, M. . A Community Oriented Primary Care Demonstration Project: Refining Interventions for Cardiovascular Disease and Diabetes. Annals of Family Medicine. March/April 2004;2(2):103-109.

Plescia, M; Konen, JC; Lincourt A. The State of Community Medicine Training in Family Medicine. Family Medicine March 2002;34(3):177-82.

Plescia, M; Koontz, S; and Laurent, S. Community assessment in a vertically-integrated health care system. American Journal of Public Health. May 2001;91(5):811-814.

*Peer Reviewed Publications (continued)*

Goldberg, J; Plescia, M; and Anastasio, G. RU 486 (Mifepristone): Current Knowledge and Future Prospects. *Archives of Family Medicine*. May/June 1998; 7:219-222.

Plescia, M; Watts, R; Neibacher, S; and Strelnick, A. A multi-disciplinary health care outreach team to the homeless: The 10-year experience of the Montefiore Care for the Homeless Team. *Family and Community Health*. July 1997, 58-69.

Mauldin SK, Plescia M, Richard FA, Wyrick SD, Voysksner RD, Chaney SG. Displacement of the Bidentate Malonate Ligand from (d,l-trans-1,2-diaminocyclohexane) Malonatoplatinum (II) by Physiologically Important Compounds in Vitro. *Biochemical Pharmacology* 1988;37:3321-3333.

Mauldin SK, Richard FA, Plescia M, Wyrick SD, Sancar A, Chaney SG. High-performance liquid chromatographic separation of platinum complexes containing the cis-1,2-diaminocyclohexane carrier ligand. *Anal Biochem*. 1986 Aug 15;157(1):129-43.

## *Surveillance Reports*

Henley SJ, Richards TB, Underwood M, Eheman CR, Plescia M, McAfee T, Lung Cancer Incidence Trends Among Men and Women by Age, United States, 2005–2009. In Review: MMWR.

Klabunde CN, Joseph DA, King JB, White A, Plescia M. Vital Signs: Colorectal Cancer Screening Test Use - United States, 2012. MMWR. November 8, 2013 / 62(44);881-888

Kronin KA, Richardson LC, Henley SJ, Miller JW, Thomas CC, White A, Plescia M. Vital Signs: Racial Disparities in Breast Cancer Severity — United States, 2005–2009. November 16, 2012 / 61(45);922-926

Holman DM, Hartman AM, Perna FM, Berkowitz Z, Guy GP, Saraiya M, Plescia M. Trends in the prevalence of sunscreen use, other sun protective behaviors, and sunburn among adults aged 18-29 years—United States, 2000-2010. MMWR. May 11, 2012;61(18); 317-322.

Guy GP, Hartman AM, Holman DM, Saraiya M, Plescia M. Use of Indoor Tanning Devices by Adults in the United States, 2010. MMWR. May 11, 2012;61(18); 323-326.

Coleman King S, Klabunde CN, Brown M, Ballard-Barbash R, White MC, Thompson T, Plescia M, Cancer Screening-United States 2010. MMWR: January 27, 2012 / 61(03);41-45

Henley J, Eheman C, Richardson L, Plescia M, et al State-Specific Trends in Lung Cancer Incidence and Smoking — United States, 1999–2008. MMWR. September 16, 2011: 60(36);1243-1247.

Richardson LC, Tai E, Rim SH, Joseph D, Plescia M. Vital Signs: Colorectal Cancer Screening, Incidence and Mortality-United States, 2002-2010. MMWR. July 8 2011;60(26);884-889

Richardson LC, Rim SH, Plescia M. Vital Signs: Colorectal cancer screening among adults aged 50-75 years-United States, 2008. MMWR. July 6 2010;59(26);808-812

Richardson LC, Rim SH, Plescia M. Vital Signs: Breast cancer screening among women aged 50-74 years-United States, 2008. MMWR. July 6 2010;59(26);813-816

## *Commentaries*

Plescia M, Wong F, Pieters J, Joseph D. Future of the NBCCEDP in a Changing Healthcare Environment. In Review: Cancer

Bauer U, Plescia M. Addressing disparities in the health of American Indian and Alaskan Native people: The importance of improved public health data. American Journal of Public Health. In Press.

Plescia M, White MC. The National Prevention Strategy: Applying Scientific Evidence to Expand Mammography Utilization. American Journal of Public Health. <http://ajph.aphapublications.org/doi/pdf/10.2105/AJPH.2013.301305>

Plescia M, Richardson L, Joseph D. New Roles for Public Health in Cancer Screening. CA. 2012;64(4);217-219

Joseph DA, Degroff AS, Hayes NS, Wong FL, Plescia M. The Colorectal Cancer Control Program: Partnering to Increase Population Level Screening. Gastrointestinal Endoscopy 2011;73(11);429-434.

Belle Isle L, Plescia M, La Porta M, Shepherd W. In Conclusion, Looking to the Future of Comprehensive Cancer Control. Cancer Causes and Control. 2010;21;2049–2057

Plescia M, Bell A. A Cancer Policy Agenda for North Carolina. Invited Commentary. Special Issue on Cancer in North Carolina. North Carolina Medical Journal. 2008;69(4);289-292.

Plescia M, Engel J. Into the Future, Public Health Data Needs in a Changing State. Invited Commentary, Special Issue on Data and Health Policy. North Carolina Medical Journal. 2008;69(2);167-169.

Plescia M, Newton-Ward M. Increasing the Public's Awareness: The Importance of Patient-Practitioner Communication. Invited Commentary. Special Issue on Effective Patient-Practitioner Communication. North Carolina Medical Journal. 2007;68(5):346-348.

Devlin L, Plescia M. The Public Health Challenge of Obesity in North Carolina North Carolina Medical Journal. Invited Commentary, Special Issue on Childhood Obesity. July/August 2006;67(4):278-282.

Mensah G, Perdue WC, Plescia M, Stroup DF. Legal Frameworks for Chronic Disease Prevention. Journal of Law, Medicine and Ethics. Winter 2004; 32SS(4):35-37

Plescia, M. British Health Care. FAX: A Journal of Student Inquiry (UNC School of Medicine Research Publication) Spring 1987;2:41-43.



### ***Book Chapters***

Plescia, M; Watts, R; Neibacher, S; and Strelnick, A. A multi-disciplinary health care outreach team to the homeless: The 10-year experience of the Montefiore Care for the Homeless Team. In Sebastian, J and Bushy, A (ed). *Special Populations in the Community: Advances in Reducing Health Disparities*. Aspen pub. 1999.

Krompinger, J. and Plescia, M. Low Back Pain. In Kozol, D; Fromm, K; and Konen, J.(ed). *When to Call the Surgeon in Primary Care*. F.A. Davis pub. 1999.

### ***Other***

Plescia M, Groblewski M. A community-based partnership to address barriers to physical activity in an African American community [abstract]. *Preventing Chronic Disease* [serial online] 2005 April. [http://www.cdc.gov/pcd/issues/2005/apr/04\\_0142m.htm](http://www.cdc.gov/pcd/issues/2005/apr/04_0142m.htm).

Plescia, M. Book Review. *Primary Care Management: Cases and Discussions*. *Social Science and Medicine*. November 2001; 54(1): 165-166.

Plescia, M. Book Review. *Homelessness and Ill Health*. *Social Science and Medicine*. July 17 1999; 49(2): 291-292.

# **CURRICULUM VITAE**

## **Michael R. Kurman, M.D.**

**OFFICE ADDRESS:** 469 West Saddle River Road  
Upper Saddle River, NJ 07458  
**PHONE:** 201-236-9730  
**FAX:** 201-760-8894  
**CELLULAR:** 201-410-3205  
**e-mail:** [mkurman@mkurmanconsulting.com](mailto:mkurman@mkurmanconsulting.com)  
**Website:** [www.mkurmanconsulting.com](http://www.mkurmanconsulting.com)

### **EDUCATION:**

1973                      B.S. in Biology, Summa Cum Laude  
Syracuse University, Syracuse NY

1977                      Doctor of Medicine  
Cornell University Medical College, New York, NY

### **ACADEMIC APPOINTMENTS:**

Adjunct Associate Professor of Epidemiology and Health Promotion, Master of Clinical Trials Program,  
New York University, 2004 - Present

Adjunct Professor for Pharmaceutical Technology Management, Wesley J. Howe School of Technology  
Management, Stevens Institute of Technology, 2006 – 2009

### **BOARD MEMBERSHIP**

Member of the Board of Directors, Avalon Pharmaceuticals, 2005 – 2009

Member of the Board of Directors, Thallion Pharmaceutidals, 2008 – 2010

### **COMMUNITY SERVICE**

Member, Upper Saddle River Board of Health, 2009 – 2014 (appointed President of the Board, May,  
2013)

Commissioner, Northwest Bergen Regional Health Commission, 2009 – 2014

Member, Syracuse University Biology Alumni Board, 2006 - Present

## PROFESSIONAL EXPERIENCE

### Current

#### **President**

Michael Kurman Consulting

Head of independent consultancy providing strategic consulting services to the pharmaceutical, biotechnology and healthcare industries. Consulting engagements focus on design of clinical development planning; protocol design; due diligence for in-licensing and capital investment; portfolio management and assessment; selection of investigators; and management of key opinion leader relationships. Regulatory activities include assistance with IND applications; responsibility for the clinical sections of NDAs/BLAs; leading Sponsor-FDA meetings; formulating regulatory strategy; and serving as medical monitor, including composing/reviewing serious adverse event narratives and submitting expedited safety reports to health authorities. Marketing activities include assisting marketing and communication organizations with competitive assessment; strategic and medical focus for advertising campaigns; medical review of communications materials; salesforce training; KOL interviews.

#### **Member of the Board of Directors**

Avalon Pharmaceuticals (2004 – 2008)

Member of the Nominating Committee (2006 – 2007)

Chairman, Compensation Committee (2007 - 2008)

#### **Member of the Board of Directors**

Thallion Pharmaceuticals (2008 – 2010)

Member of the Compensation Committee (2008 – 2010)

#### **Member of the Scientific Advisory Board**

Thallion Pharmaceuticals (2007 – 2010)

#### **Member of the Scientific Advisory Board**

Locus Pharmaceuticals, 2004 - 2008

#### **Member of the Scientific Advisory Board**

Biothera, 2008 -2010

### 1998 - 2000

#### **Vice President, Clinical and Scientific Operations**

Quintiles, Quintiles Oncology Therapeutics Division, Cranford, NJ

Responsible for clinical monitoring, investigator relations, medical affairs and drug safety reporting for contract research division dedicated to Phase I – IV oncology clinical trials; wrote oncology protocols and consulted on clinical trial design with sponsors; consulted on regulatory strategy and clinical development plans with sponsors; reviewed integrated reports and regulatory submissions; primary contact to consortia of oncology investigators in academic and non-academic settings; oversaw oncology training program for CRAs and project managers; oversaw group of about 60 individuals; direct reports were two physicians and a drug safety nurse, the Director of Clinical Operations; and the Associate Director for Investigator Relations; reported to Sr. Vice President, Quintiles Oncology Therapeutics. Developed strategic alliance with national

consortium of academic oncology centers; developed second strategic alliance with national consortium of community cancer centers; developed strategic alliance with national oncology managed care organization; contact to Business Development group for proposal/presentation strategy.

**1996 - 1998**

**Vice President, Clinical Operations**

Quintiles, Innovex Division, Parsippany New Jersey

In charge of all clinical research projects conducted by contract research company primarily devoted to late stage (Phase 3B/4) clinical trials in a broad range of therapeutic areas, including cardiovascular, endocrinology, oncology, HIV, transplantation and CNS; directly responsible for project management, clinical monitoring, data management, medical affairs, drug safety and regulatory affairs; managed group of approximately 80 individuals; set overall business strategy for US clinical department of Innovex; set-up “war-room” for conduct of large simple trials using optical scanning technology; re-vamped all SOPs; instituted training procedure for new hires (“Innovex University”); initiated internship program with local school of pharmacy; reported to President of Innovex US.

**1995 – 1996**

**Vice-President, Clinical Research**

U.S. Bioscience, West Conshohocken, PA

In charge of all clinical research conducted in North America for U.S. Bioscience; formulated clinical development plan and long-term research strategy for all U.S. Bioscience products in conjunction with overall corporate strategy; authored protocols, selected investigators and managed clinical trials in Phases 1 - 4; responsible for Clinical Operations, Biostatistics, Medical Writing and Clinical Information; liaison for all medical/clinical information with Marketing, Sales, Finance; marketing partners; responsible for all safety reporting to FDA. Personally wrote all SOP's pertaining to Clinical Operations, re-vamped clinical filing system, installed new information management technology, undertook process mapping to improve efficiency of clinical trials startup, monitoring and data retrieval; reported to CEO. Designed and managed clinical program that resulted in successful NDA for radioprotectant.

**1993 – 1995**

**Senior Director of Cancer Therapeutics**

Cytogen Corporation, Princeton, NJ

Project leader for radiopharmaceutical for the treatment of bone metastases; authored protocol and managed worldwide Phase 3 trials, including studies in US, Canada, UK, France, Switzerland; was personally responsible for NDA filing and for communications with FDA; was primary liaison between CYTOGEN, its CRO's and European licensee; managed yearly research budget in excess of \$2 million; reported to VP of Clinical Investigations. Designed and managed program that resulted in successful for agent for metastatic bone disease.

**1989 – 1992**

**Director of Clinical Research, Oncology and Allergy**

Janssen Research Foundation; Titusville, NJ

Initiated and managed Phase 1 - 3 trials with differentiating agent for metastatic prostate cancer and hormonal agent for metastatic breast cancer; project leader for NDA for topical anti-histamine; primary contact for clinical discussions and meetings with FDA; managed group of approximately nine, including Assoc. and Asst. Directors, Manager, CRA's; reported to VP of Clinical Research. Also served as technical support for VP Business Development in scientific and clinical evaluation of licensing opportunities for oncology/immunology compounds. Clinical team member for successful NDA of immunotherapeutic for colon cancer.

- 1982 – 1989**            **Private Practice of Medical Oncology**  
Middlesex Oncology P.A., Edison, NJ
- 1980 – 1982**            **Fellow in Neoplastic Diseases**  
Mt. Sinai Medical Center, New York, NY
- 1979 – 1980**            **Clinical Instructor in Medicine**  
State University of New York - Upstate Medical Center; Syracuse, NY
- 1978 – 1979**            **Resident in Internal Medicine**  
State University of New York - Upstate Medical Center; Syracuse, NY
- 1977 – 1978**            **Intern in Internal Medicine**  
State University of New York - Upstate Medical Center; Syracuse, NY

#### **WORK-RELATED EXPERIENCE**

- 1996 – 2000**            **Continuing Medical Education Committee**  
Drug Information Association
- 1992 – 1993**            **Pharmacoeconomic Task Force**  
Janssen Research Foundation
- 1984 – 1989**            **Medical Director**  
Rahway Hospital Hospice, Rahway, NJ
- 1987 – 1989**            **Field Liaison, Commission on Cancer**  
American College of Surgeons
- 1983 – 1985**            **Instructor in Medicine**  
Perth Amboy General Hospital, Perth Amboy, NJ
- 1984 – 1989**            **Utilization Review Committee**  
John F Kennedy Hospital, Edison, NJ
- 1985 – 1989**            **Quality Assurance Committee**  
Rahway Hospital, Rahway, NJ
- 1983 – 1985**            **Committee on Professional Education**  
American Cancer Society

**CERTIFICATION:**

1975 National Board of Medical Examiners, Part I  
1977 National Board of Medical Examiners, Part II  
1978 National Board of Medical Examiners, Part III  
1981 American Board of Internal Medicine  
1985 American Board of Internal Medicine, Subspecialty of Medical Oncology

**LICENSURE:**

New York #138327  
New Jersey #40567

**AWARDS:**

Phi Beta Kappa, Syracuse University Chapter  
Alpha Epsilon Delta, Pre-medical Honorary Society, Syracuse University Chapter  
The Dean's Research Award, Cornell University Medical College  
The National Foundation-March of Dimes Summer Research Grant  
American Cancer Society Community Appreciation Award  
The President's Award, Janssen Research Foundation

**PROFESSIONAL ORGANIZATIONS**

American Society of Clinical Oncology  
American Academy of Pharmaceutical Physicians  
American Association of Pharmaceutical Scientists  
Regulatory Affairs Professional Society  
Drug Information Association  
American Society of Hematology

**PUBLICATIONS AND PRESENTATIONS:**

1. Kurman MR and Argyris T: The proliferative response of epidermis to full thickness wounds. *Am J Path* 79:301, 1975.
2. Perth Amboy General Hospital Grand Rounds, November, 1983, Autoimmune hemolytic anemia.
3. Kampel LJ and Kurman MR: Severe leukopenia induced by aminoglutethimide. *Can Treat Rep* 68:1277, 1984.
4. Kurman MR: Decisions about CPR (letter). *NEJM* 318:1273, 1988.
5. Kurman MR: Palliative chemotherapy, in Patt R (ed): *Problems in Cancer Pain Management: A Multidisciplinary Approach*, Philadelphia, J.B. Lippincott Company, 1992.
6. Kurman MR: Levamisole and melanoma (letter). *J Clin Oncol* 9:1714, 1991.
7. Kurman MR: Recent clinical trials with levamisole. Presented at the New York Academy of Sciences meeting on immunomodulator therapy, July, 1992, Washington, DC.

8. Seidmon EJ, Trump DL, Kreis W, Hall SW, Kurman MR, Ouyang SP: Phase I dose escalation study of liarozole in patients with Stage D, hormone-refractory carcinoma of the prostate. Presented at the annual meeting of the Society for Surgical Oncology, April, 1993.
9. Strauss L, Herbst L, Kurman, MR: Comparison of the cost-effectiveness of DURAGESIC and infusional parenteral morphine. Presented at the 15<sup>th</sup> annual meeting of the National Hospice Organization, Salt Lake City, October 13-16, 1993.
10. Kurman, M: Nuclear Medicine in Oncology. Presented at the Central Chapter of the Society of Nuclear Medicine's Road Show, Minneapolis, March 5, 1994.
11. Serafini AN, Elgarresta, Mallin W, Watson C, Gomez CA, Vargas-Cuba E, Gordon E, Kurman M: Sm-153-EDTMP as a palliative agent for patients with bone metastases. *Jour Nuc Med* 35:235P, 1994.
12. Budd GT, Bukowski RM, Adelstein D, Pelley R, Olencki T, Petrus J, McLain D, Conlon J, Kurman M, Capizzi RL, Ganapathi R: Mature results of a randomized trial of carboplatin and amifostine vs carboplatin alone in patients with advanced malignancies. *ASCO Proceedings, Volume 15, 1996.*
13. Stansell JD, Sattler FR, Dube M, Koda RT, Lee WL, Chatterjee DJ, Sharpe E, Capizzi RL, Kurman MR: Randomized trial of trimetrexate, leucovorin and dapsone vs. trimethoprim/sulfamethoxazole for *Pneumocystis carinii* pneumonia. *ASCO Proceedings Volume 15, 1996.*
14. Blanke C, Kasimis B, Schein P, Capizzi RL, Kurman M: A Phase II trial of trimetrexate, 5-fluorouracil and leucovorin in patients with unresectable or metastatic colorectal cancer. *ASCO Proceedings, Volume 15, 1996.*
15. List AF, Heaton R, Glinsmann-Gibson B, Brasfield F, Crook L, Taetle R, Kurman M: A Phase I/II clinical trial of amifostine in patients with myelodysplastic syndrome (MDS): promotion of multilineage hematopoiesis. *ASCO Proceedings, Volume 16, 1997.*
16. Kurman, M: New paradigms in cancer clinical trials. Presented at the Fall Meeting of the Association of Community Cancer Centers, Long Beach, CA, September, 1999.
17. Paterson AHG, Powles TJ, Kanis JA, McCloskey EV, Archambault WT, Kurman MR: Effect of clodronate on time to occurrence of skeletal complications in patients with breast cancer and bone metastases. Abstract submitted to the 24<sup>th</sup> Annual San Antonio Breast Cancer Symposium.
18. Kurman MR, Verastegui E, Barrera J, et al. IRX-2 protocol improves outcome in head and neck cancer. *Proc Amer Soc Clin Oncol* 22:755, 2003.
19. Kurman MR. The development of cancer vaccines. *Regulatory Affairs Focus* 9:12, 2004
20. Heron DE, Gerszten K, Brufsky AM, Kurman M. The effect of chemotherapy and external beam radiotherapy on bone marrow toxicity of radionuclides in the treatment of bone metastases secondary to breast cancer. *Proc Amer Soc Clin Oncol* 23:75, 2004
21. Rodon J, Patnaik A, Stein M, Tolcher A, Ng C, Dias C, Kurman M, Greig G, Kurzrock R, Rubin E. A phase I study of q3W R1507, a human monoclonal antibody IGF-1R antagonist in patients with advanced Cancer. Presented at the American Society of Clinical Oncology Annual Meeting, June 1 – 5, 2007, Chicago, IL.

22. Modiano M, Plezia P, Baram J, Catane R, Cohn A, Basche M, Kurman M, Tapolsky G, Yancik S. A phase I study of TPI 287, a third generation taxane, administered every 21 days in patients with advanced cancer. *Jour Clin Oncol* 25 (suppl 18):114s (abstract 2569), 2007
23. Hwang JJ, Marshall, JL, Ahmed T, Chun H, Basche M, Cohn A, Kurman M, Tapolsky G, Allen E. A phase I study of TPI 287: A third generation taxane administered weekly in patients with advanced cancer. *Jour Clin Oncol* 25 (suppl 18):115s (abstract 2575), 2007
24. Heron DE, Brufsky A, Beriwal S, Kurman, M. Myelotoxicity of samarium Sm 153 lexidronam in patients receiving prior treatment with chemotherapy or radiotherapy. *Ann Oncol* 19:1639 – 1643, 2008
25. Halstenson CE, Gargano MA, Kurman MR, Walsh R, Fu CH and Patchen ML. Phase 1, Randomized, Double-Blind, Placebo-Controlled, Single-Dose, Dose-Escalation Study of Imprime PGG® Injection (Imprime PGG) in Healthy Subjects. Presented at the 23<sup>rd</sup> Annual Meeting of the International Society for Biological Therapy of Cancer, San Diego, 2008.
26. Halstenson CE, Gargano MA, Kurman MR, Walsh R, Theoharis N, and Patchen ML. Phase 1, Randomized, Double-Blind, Placebo-Controlled, Multiple-Dose, Dose-Escalation Study of Imprime PGG® Injection (Imprime PGG) in Healthy Subjects. Presented at the 23<sup>rd</sup> Annual Meeting of the International Society for Biological Therapy of Cancer, San Diego, 2008
27. Tamayo ME, Conrelío GH, Bautista JB, Flores ML, Kurman MR, Paul MM, Gargano MA and Patchen ML. A Phase 1b/2 Dose-Escalating, Safety and Efficacy Study of Imprime PGG, Cetuximab and Irinotecan in Patient with Advanced Colorectal Cancer. *Journal of Clinical Oncology*, 2007 ASCO Annual Meeting Proceedings Part I. Vol 25, No. 18S (June 20 Supplement), 2007: 2575.
28. Workshop Leader for “Working with Specialized Oncology CROs” at the ExL Pharma Partnerships in Oncology Clinical Trials Conference, Philadelphia, January 26, 2009
29. Dickson MA, LoRusso P, Sausville EA, Rao N, Kobayashi E, Kurman MR, Akinaga S, Schwartz GK. Open-label, sequential, ascending, multi-dose, phase I study of KW-2450 as monotherapy in subjects with previously treated advanced solid tumors. *J Clin Oncol* 29: 2011 (suppl; abstr 3078).
30. Kurman, M. Drug reactions and new prescriptions (Letter to the editor). *The American Scholar*, 80:3, Autumn, 2011.
31. Akers-Smith SA and Kurman M. Strategies for early phase oncology clinical research. *SCRIP*, Oct, 2012.
32. Mahalingam D, Wilding G, Denmeade S, Sarantopoulos J, Cosgrove D, Cetnar J, Azad N, Bruce J, Kurman M, Carducci M. A first-in-human, Phase 1 clinical study of the safety, tolerability, and pharmacokinetics of G-202, a thapsigargin-based PSMA-activated prodrug in patients with advanced solid tumors. Presented at the 24<sup>th</sup> EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics, Dublin, November, 2012.



33. Cavenagh J, Baylon H, Caguioa PB, Davies FE, Gharibo M, Akinage S, Kurman M, Novak B, Yong K. An open-label, dose escalation, multicenter Phase 1/2 study of KW-2478 in combination with bortezomib in subjects with relapsed and/or refractory multiple myeloma. Accepted for presentation at the 2014 Annual Meeting of the American Society of Hematology, New Orleans.

## **PATENTS**

Patent #8409574, "Taxane Analogs for the Treatment of Brain Cancer," issued 02 APRIL 2013

## ***About Michael Kurman Consulting, LLC***

Dr. Michael Kurman has been in the healthcare field for 28 years, first as a physician-investigator, later as a pharmaceutical executive and now as a consultant to the healthcare, pharmaceutical and biotech industries.

Examples of some projects completed by Michael Kurman Consulting, LLC include:

- Advised the European subsidiary of a Japanese pharmaceutical company in organizational structure for its Clinical Research Division
- Trained a newly assembled pharmaceutical sales force at the time of launch of a new breast cancer drug
- Assisted several privately held biotech companies in the raising of venture capital
- Assisted a small pharmaceutical company with clinical developmental and regulatory strategy, and presenting the company's position at a pre-NDA meeting at the FDA
- Assisted a hospital placed on clinical hold by the FDA in re-organizing their IRB and clinical research departments
- Designed the U.S. clinical development plan for a growth factor inhibitor sponsored by a Japanese pharmaceutical company and leading an expert panel to discuss the development plan
- Designed the global clinical development plan for an agent for the treatment of bone metastases for a European pharmaceutical company
- Designed the Phase 1 studies for a novel chemotherapy agent sponsored by a major U.S. pharmaceutical and healthcare company
- Wrote the business plan for a privately held medical informatics and data-management company concentrating in the oncology area

- Assisted a company in its due diligence in anticipation of purchasing a CRO
- Designed and managed the Phase 1 program of a novel cancer immunotherapeutic for a privately held biotech company
- Designed the clinical trials for a Phase 4 program for a major global pharmaceutical company in anticipation of the launch of a novel oncology product
- Advised a medical education company in their efforts to obtain certification to provide continuing education credit
- Performed medical and clinical due diligence for the US subsidiary of a European pharmaceutical company attempting to licensing in several oncology products
- Wrote the Integrated Summary of Safety for NDA and participating in pre-NDA meeting for agent for metastatic bone disease
- Served as medical monitor for clinical trials of a breast cancer diagnostic product
- Served on the Medical Advisory Board of a medical education company
- Assisted a major biotech company in analysis of safety data from a Phase 1 study of new proteasome inhibitor
- Developed several Phase 4 studies for a global pharmaceutical company for a recently launched growth-factor inhibitor drug
- Assisted a pharmacogenomics company with licensing strategy and due diligence
- Advised a venture capital company regarding due diligence and investments in biotechnology
- Advised a biotechnology company with a unique anti-cancer platform on development and regulatory strategy

- Assisted a major European pharmaceutical company in development of a new chemotherapy product for colorectal cancer
- Assessed the clinical development plan for a biotechnology company with a vascular targeting agent
- Assisted a Canadian pharmaceutical company with preparation and submission of a US IND for a novel anti-cancer drug
- Assisted the same Canadian pharmaceutical company in raising venture capital
- Assisted a major global pharmaceutical company with the development of an agent for the treatment of bone metastases, including authoring two Phase 3 pivotal protocols, serving as a clinical advisor in an end of Phase 2 meeting at FDA and participating in a special protocol assessment
- Assisted a small natural products company in the development of a new cytotoxic derived from plant biomass
- Assisted a small pharmaceutical company with a clinical development plan for a unique anti-anginal product
- Assisted a US pharmaceutical company (study design, database design, data analysis) with a Phase IV trial of a calcium channel blocker used during angioplasty
- Authored the Phase 1 protocol and the clinical portion of the IND and served as the clinical representative during the pre-IND meeting with the FDA for a novel monoclonal antibody targeting a growth factor receptor of a major international pharmaceutical company
- Authored the Phase 1 protocol, the investigator's brochure and the clinical portion of the IND for a novel anti-mitotic agent and led the pre-IND teleconference for a small pharmaceutical company

- Authored the Phase 3 clinical development plan for a novel agent that induces heat shock protein 90 for a small pharmaceutical company
- Authored a global clinical development plan for a vascular disrupting agent for an Australian company
- Authored a clinical development plan for a gene-therapy product for the treatment of ovarian cancer
- Authored a global clinical development plan for 2 products with unique mechanisms of action for a Canadian pharmaceutical company
- Assisted a European pharmaceutical company with their pediatric investigational plan for the EMA
- Leading the development effort for a radiation protection agent for patients with head and neck cancer
- Assisted the US subsidiary of a Japanese pharmaceutical company in performing medical due diligence for several oncology drug in-licensing opportunities
- Assisting a Japanese-based global pharmaceutical company in the development of several compounds for a variety of malignancies
- Performed due diligence for the US subsidiary of a major Japanese pharmaceutical company on the successful in-licensing of a novel compound for the treatment of Hodgkin's Disease
- Assisted a marketing/communications company making a presentation to a major US biotechnology company with strategic and medical focus for an advertising campaign for a monoclonal antibody used in the treatment of non-Hodgkin's lymphoma; presented at the pitch to the client
- Serving as the medical monitor for a Phase 1 study in patients with advanced solid tumors sponsored by a developmental stage pharmaceutical company

- Serving as the medical monitor for several Phase 1/2 studies of a monoclonal antibody under development for various malignancies sponsored by a development stage biotechnology company
- Designed the clinical development plan for 2 oncology biosimilar products for ex-US company

**Curriculum Vitae**  
**Lee M. Greenberger, Ph.D.**  
Work: 914-821-8415  
E-mail: lee.greenberger@lls.org

**Summary**

- **Experienced scientist and leader with a 24-year record of discovering and advancing more than 10 novel therapeutics for the treatment of cancer from the laboratory to the clinic**
- **Experience at non-profit organization overseeing \$75 M annual portfolio consisting of 320 active grants and 20 individual assets focused in hematological malignancies**
- **Leadership experience within mid-size biotech (oversee 60-person unit) as well as interfacing with senior leadership within biotech and big pharma**
- **Internationally recognized scientist through the advancement of novel cancer therapies and approximately 90 publications**
- **Executive level experience within business development unit for in/out-licensing Oncology and Immunology assets for a large pharmaceutical firm**
- **Wide knowledge base in all facets of Research and Development including strategic program design, IND-enabling work integrating large teams, laboratory design, biologic manufacturing, in/out-licensing and budgeting**

**Experience**

**2013-            Leukemia and Lymphoma Society**  
**Chief Scientific Officer**

**2012-2013    Bristol-Myers Squibb**  
**Global Therapeutic Area Head for Oncology and Immunology**  
**Search and Diligence**  
**Strategic Transaction Group**

Key Accomplishments

- Executed strategic in-licensing and out-licensing plans for Oncology and Immunology including examination of 250 opportunities and approximately 8 due diligence exercises with first 10 month since starting
- Working with Senior Management to design and implement new external opportunity strategies for 2013

**2006-2012    Enzon Pharmaceuticals, Piscataway, NJ**

## Vice President, Research

### Key Accomplishments

- Re-built and direct unit of > 60 scientists with Oncology focus (2006-2010); hired >25 new scientists in research and process development
- Oversee and coordinate Pharmacology, Toxicology, Process Development, Analytical and Chemistry efforts; peak operating budget > \$30 M
- Filed 6 new INDs (includes PEG-SN38 and LNA- RNA antagonists)
- Oversee design, construction, and activation of process development laboratory for toxicology and phase I material (>\$12M investment)
- Oversee development of two new APIs (Asparaginase and Adenosine Deaminase) to replace marketed products. New API FDA-approved for Asparaginase. Products sold to Sigma-Tau Pharmaceuticals in 2010.
- Designed and implemented collaboration with Santaris Pharma for discovery of novel LNA oligonucleotides against 8 targets in cancer
- Restructuring company to be a full-fledged biotech company based on research and development including 40% down-sizing of unit after sale of marketed products (beginning 2010)
- Senior most person leading Research and Production after departure of CSO (2011); report directly to Principal Executive Officer (2011)
- Co-lead BD effort for China out-licensing initiative (2011)

## 2005-2006 Cancer Therapeutics Research, Johnson & Johnson Sr. Research Fellow & Team Leader, Raritan, NJ

### Key Accomplishments

- Directed effort of 25 scientist in Oncology Discovery
- Led 3 research programs in Oncology to go/no-go status for FIH decision within 1<sup>st</sup> nine months on site
- Initiated new research programs in oncology
- Raritan site representative for Biomarker Strategic Initiative
- Identified and coordinated 2 early phase 0/I programs suitable for in-licensing
- Core member scientific subteam of Therapeutic Area Operating Committee

## 1990-2005 Oncology Research, Wyeth Pharmaceuticals (formerly Lederle Laboratories, American Cyanamid)

**Sr. Director** (2001- 2005), **Director** (2000- 2001), **Associate Director** (1997-2000),  
**Group Leader** (1991-1997), **Sr. Research Biochemist** (1990-1991)

### Key Accomplishments

- Developed 8 of the 25 small molecules that entered Wyeth's Oncology pipeline during tenure. Five of the seven entered clinical trials; four advanced to Phase II (EKB-569, MAC-321, ERA-923, HTI-286).



- Discovery Project Team Leader for 6 projects. Directed and coordinated research efforts for 10-25 team members / project
- Research Project Director for Joint Venture with Taxolog, Inc.
- Principle Author of Pharmacology Section for 5 IND filings.
- Development Strategy Team Member (representing pre-clinical pharmacology) for 5 projects in clinical testing
- Design and implemented 10 programs for the discovery of signal transduction (kinase) inhibitors, hormone receptor inhibitors, tubulin inhibitors, and drug transport inhibitors
- President's Award (2002); Above and Beyond Award (2001, 1999, 1997)
- Hired 6 PhDs and 14 non-PhDs
- Supervised National Cooperative Drug Discovery Grant (1995-2000). Principle investigator for NCDDG renewal (2000-2005)

**1986-1997**

**Albert Einstein College of Medicine**

Department of Molecular Pharmacology

Laboratory of Dr. Susan Horwitz

**Visiting Assistant Professor** (1990-1997), **Instructor** (1988-1990), **Research Associate** (1986-1988)

Key Accomplishments

- Author of >10 full-length papers on ABC transporters in drug resistance. Nationally recognized expert in the study of drug interaction with the drug resistance pump known as P-glycoprotein.
- Leukemia Society of America Special Fellow
- Co-principal investigator: Bristol-Myers Drug Resistance Grant.

**1984-1986**

**Columbia University**

Department of Anatomy and Cell Biology

Post-doctoral Associate

Key Accomplishments

- Identified novel membrane proteins on growing neurons
- Developed expertise in the study of glycoproteins

**Education:**

Emory University, Ph.D., Anatomy, 1984

University of Rochester, B.A., Neuroscience, 1977

**Grants, Honors, and Speeches:**

- 2104 Moderator, AAADV Session focused on CAR T therapy, Washington, DC
- 2014 Invited Speaker: DTCC talk on HSCT, Jersey City, NJ
- 2014 Invited Speaker: Diamond Ball LLS event, Buffalo, NY

Lee Greenberger, CV

- 2011 Invited Speaker, TIDES, Boston, MA
- 2010 Invited Speaker, EuroTIDES, Barcelona, Spain
- 2009 Invited Speaker, Discovery on Target: RNA Section. Boston, MA
- 2009 Invited Speaker, RNA Interference Summit, San Francisco, CA
- 2009- Education Committee Member, AACR (3 year appointment)
- 2008 Invited Speaker, EuroTIDES, Dusseldorf, Germany
- 2008 Invited Speaker, 10<sup>th</sup> International Symposium on Angiogenesis, February San Diego , CA
- 2005 Principle Investigator, NCCDG (2005)
- 2003 Invited speaker, SRI symposium on Growth Factor Receptors, May 5-6, 2003, Philadelphia, PA.
- 2001 Invited speaker, SRI symposium on Protein Kinases in Drug Discovery and Development, October 15-16,2001, Newark, NJ.
- 2000 National Cooperative Natural Products Drug Discovery Group. "Anticancer Agents from Unique Natural Product Sources." Funded 10/00-9/05. Co-Program Leader with Dr. P. Frost
- 1994 Chairperson, Symposium on "Drug Resistance in Microbes, Parasites, Viruses, and Tumors," 21st National Medicinal Chemistry Symposium, Salt Lake City, UT
- 1993-1995 American Cyanamid Research Grant with Dr. E. Sztul, Princeton University. "Molecular mechanisms mediating multiple drug resistance in tumor cells"
- 1993 Co-chairperson, Symposium, "Membrane Transporters in Multiple Drug Resistance and Cystic Fibrosis," New Academy of Sciences, NY
- 1992 Invited speaker, Calcium Antagonists: Pharmacology and Clinical Research., Houston, TX
- 1991 Co-chairperson, Minisymposium, American Association for Cancer Research, Houston, TX
- 1988-1990 Co-principal investigator, Bristol-Myers Tumor Resistance Grant
- 1987-1990 Leukemia Society of America Special Fellow

- 1987                      Invited speaker, Gordon Research Conference on Chemotherapy of Experimental and Clinical Cancer
- 1984-1986                National Research Service Award - NIMH Training Grant
- 1985                      Travel Fellowship for Workshop on Neuronal Membrane and Development in Cargese, Corsica

**Professional Organizations:**

American Association for the Advancement of Science  
American Society for Cell Biology  
American Association for Cancer Research  
American Society for Biochemistry and Molecular Biology

**Peer Review Activities:**

Grant reviewer: Am. Cancer Society, John Sealy Memorial Endowment Fund, Dept. of Veteran Affairs-Research and Development, American Association for Cancer Research  
Manuscript reviewer: J. Biol. Chem., Cancer Res., J. Natl. Cancer Inst., Biochem. Pharmacol., Biophys. J., Oncol. Res., Mol. Pharmacol., Biochemistry, Mol. Cancer Thera., J. Med Chem., J. Mol. Med.

**Bibliography : >80 full-length articles**

1. Morrell, J.I., Greenberger, L.M. and Pfaff, D.W. (1981). Comparison of horseradish peroxidase visualization methods: Quantitative results and further technical specifics. J. Histochem. Cytochem. 29, 903-916.
2. Morrell, J.I., Greenberger, L.M. and Pfaff, D.W. (1981). Hypothalamic, other diencephalic, and telencephalic neurons that project to the dorsal midbrain. J. Comp. Neurol. 201, 589-520.
3. Greenberger, L.M. and Besharse, J.C. (1983). Photoreceptor disc shedding in eye cups: Inhibition by deletion of extracellular divalent cations. Invest. Ophthalmol. Vis. Sci. 28, 1456-1464.
4. Greenberger, L.M. and Besharse, J.C. (1985). Stimulation of rod photoreceptor disc shedding by aspartate, glutamate, and other amino acids. J. Comp. Neurol. 239, 361-372.
5. Greenberger, L.M. and Pfenninger, K.H. (1986). Membrane glycoproteins of the nerve growth cone: diversity and growth-associated oligosaccharides. J. Cell Biol. 103, 1369-1382.
6. Greenberger, L.M., Williams, S.S., and Horwitz, S.B. (1987). Biosynthesis of

- heterogeneous forms of multidrug resistance-associated glycoproteins. *J. Biol. Chem.* 262, 13685-13689.
7. Greenberger, L.M. (1987). Protein trafficking: the sorted details. *Einstein Quart. J. Biol. and Med.* 5, 98-99.
  8. Greenberger, L.M., Lothstein, L.L., Williams, S.S., and Horwitz, S.B. (1988). A family of multidrug resistance-associated glycoproteins: distinct precursors are overexpressed in independently isolated cell lines. *Proc. Natl. Acad. Sci. USA* 85, 3762-3766.
  9. Greenberger, L.M., George, E., Williams, S.S., Ling, V., and Horwitz, S.B. (1988). Electrophoretic analysis of P-glycoproteins produced by mouse J774.2 and Chinese hamster ovary multidrug-resistant cells. *J. Natl. Cancer Inst.* 80, 506-510.
  10. Horwitz, S.B., Goei, S., Greenberger, L.M., Lothstein, L., Mellado, W., Roy, S.N., Yang, S.N., C.-P., and Zeheb, R. (1988). Multidrug resistance in the mouse macrophage-like cell line J774.2 in Mechanisms of Drug Resistance in Neoplastic Cells (Woolley III, P.V., and Tew, K.D., eds.) Academic Press, NY, pp. 223-242.
  11. Horwitz, S.B., Liao, L.-L., Greenberger, L.M., and Lothstein, L. (1988). Mode of action of taxol and characterization of a multidrug resistance cell line selected with taxol. in Resistance to Antineoplastic Drugs (Kessel, D., ed.), CRC Press, Boca Raton, pp. 109-125.
  12. Yang, C.-P.H., DePinho, S.G., Arceci, R., Greenberger, L.M., and Horwitz, S.B. (1989). Progesterone interacts with P-glycoproteins in multidrug-resistant cells and in the endometrium of gravid uterus. *J. Biol. Chem.* 264, 782-788.
  13. Greenberger, L.M., Lothstein, L. and Horwitz, S.B. (1989) Heterogeneous forms of P-glycoprotein in multidrug resistant J774.2 cells. Colloque INSERM (Anticancer Drugs, H. Tapiero, J. Roberts, and T.J. Lampidis, eds. John Libbey Eurotext Ltd., London) 191, 263-275.
  14. Lothstein, L., Hsu., S.I., Horwitz, S.B. and Greenberger, L.M. (1989) Alternate overexpression of two P-glycoprotein genes is associated with changes in multidrug resistance in a J774.2 cell line. *J. Biol. Chem.* 264, 16054-16058.
  15. Greenberger, L.M., Croop, J.M., Horwitz, S.B. and Arceci, R.J. (1989). P-glycoproteins encoded by mdr1b in murine gravid uterus and multidrug resistance tumor cell lines are differentially glycosylated. *FEBS Lett.* 257, 419-421.
  16. Greenberger, L.M., Yang, C.-P. H., Gindin, E., and Horwitz, S.B. (1990). Photoaffinity probes for the alpha-adrenergic receptor and the calcium channel bind to a common domain in P-glycoprotein. *J. Biol. Chem.* 265: 4394-4401.
  17. Yang, C.-P.H., Cohen, D., Greenberger, L.M., Hsu, S. I.-H., and Horwitz, S.B. (1990). Differential transport properties of two mdr gene products are distinguished by progesterone. *J. Biol. Chem.* 265: 10282-10288.

18. Greenberger, L.M. (1990). Photoaffinity labeling of the multidrug-resistant gene product, P-glycoproteins. Dupont Biotech Update: p. 57-58.
19. Yang, C.-P.H., Greenberger, L.M., and Horwitz, S.B. (1991). Reversal of multidrug resistance in tumor cells. in Synergism and Antagonism in Chemotherapy (D. Rideout, and T.-C. Chow ed.), Academic Press, NY. 311-338.
20. Greenberger, L.M., Hsu, S. I.-H., Yang, C.-P., Lothstein, L., Cohen, D., Han, E., and Horwitz, S.B. (1992). A comparison of the structure, function, and expression of P-glycoproteins encoded by mdr1a and mdr1b in mouse. in Drug Resistance as a Biochemical Target in Cancer Chemotherapy. pp. 63-95.
21. Greenberger, L.M., Lisanti, C.J., Silva, J.T., and Horwitz, S.B. (1991). Domain mapping of the photoaffinity drug binding sites in P-glycoprotein encoded by mdr1b. J. Biol. Chem. 266: 20744-20751.
22. Greenberger, L.M. (1993). Reversal of P-glycoprotein-mediated multidrug resistance in tumor cells by calcium channel antagonists. in Calcium Antagonists: Pharmacology and Clinical Research. (T. Godfraind, S. Govani, R.Paoletti, and P. M. Vanhoutte, eds.), Kluwer Academic Press. Boston, MA. NY. pp. 363-368.
23. Kirschner, L. S., Greenberger, L. M., Hsu, S. I. H., Yang, C.P.H., Cohen, D., Piekarz, R. L., Castillo, G., Han, E. K. H., Yu, L., and Horwitz, S. B. (1992). Biochemical and genetic characterization of the multidrug resistance phenotype in murine macrophage-like J774.2 cells. Biochemical Pharmacol. 43: 77-87.
24. Greenberger, L. M. (1993). Major photoaffinity drug binding sites for iodoaryl azidoprazosin in P-glycoprotein are within, immediately C-terminal to, transmembrane 6 and 12. J. Biol. Chem 268: 11417-11425.
25. Greenberger, L. M., Cohen, D., and Horwitz, S. B. (1994). *In vitro* models of multiple drug resistance. in Cancer Treatment and Research. (L.J. Goldstein and R. F. Ozols, eds.), Kluwer Academic Publishers, Norwell, MA. 69-106.
26. Morris, D., Greenberger, L. M., Bruggemann, E. P., Cardarelli, C., Gottesman, M. M., Pastan, I., and Seamon, K. (1994). Localization of the labeling sites of forskolin to both halves of P-glycoprotein: similarity of the sites labeled by forskolin and prazosin. Mol. Pharmacol. 46: 329-337.
27. Greenberger, L. M. and Ishikawa, Y. (1994). ATP-binding cassette proteins: common denominators between ion channels, transporters, and enzymes. Trends in Cardiovas. Med. 4:193-198.
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**Patents:**

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Loganzo Jr., F., Greenberger L. M., Tan, X., Wissner, A. Assays to identify irreversible binding inhibitors of receptor tyrosine kinases. PCT/US 2005/016951. Filed May 2005

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Greenberger, L.M., Qu, T., Zhang, Y. Methods of treating kinase-resistant cancer with HER3 antisense oligonucleotides. US 61/413784. Filed November 2010.

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## PROFESSIONAL SUMMARY

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Results driven Regulatory Affairs executive with over 20 years experience in multinational pharmaceutical, biotech and device companies. Skilled at developing and driving execution of global regulatory strategies, business initiatives and systems development to advance business goals. Effective communicator and organizational leader with recognized ability to build productive relationships and to develop/retain highly productive and motivated teams in a matrix environment.

## EDUCATION

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### **PhD Molecular Genetics and Microbiology**

Rutgers University and the University of Medicine and Dentistry of New Jersey  
(Center for Advanced Biotechnology and Medicine, New Brunswick, NJ)

#### **Awards:**

Raymond W. Sarber Award, American Society for Microbiology  
Natl. Research Service Award/Natl. Inst. of Health Biotechnology Fellowship  
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Molecular and Cell Biology Fellowship, Rutgers University/UMDNJ

### **BS Biochemistry (Magna cum Laude)**

University of Massachusetts, Amherst MA

## PROFESSIONAL EXPERIENCE & ACCOMPLISHMENTS

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### **CYMREG CONSULTING, DOYLESTOWN, PA**

Current

#### *President & Principal Consultant*

Provide expert advice and hands-on capability in all areas of regulatory strategy and operations/submission planning with focus on providing regulatory guidance to small companies and start-ups where the need covers cross-functional regulatory requirements (Clinical, CMC, Preclinical). Services include advising on global or specific regulatory strategies and planning for projects ranging from early clinical development through post-approval, preparation of regulatory documents for submission to global health authorities, support for meetings with health authorities and assessing regulatory risks for licensing opportunities.

- Experience includes: developing regulatory strategies for clinical and pharmaceutical development of strategic new products, life cycle management and compliance of marketed products in multiple therapeutic areas (including oncology, blood products/biosurgery, and endocrine/metabolic); submission of INDs, CTAs, NDAs, BLAs, MAAs, PMA/510Ks and leading major regulatory meetings covering small and large molecules and biologic/device combination products.

### **OMTHERA PHARMACEUTICALS, PRINCETON, NJ**

2011–2012

#### *Vice President, Regulatory Affairs*

Accountable for the development and execution of regulatory strategies for global investigational and marketing applications, as well as developing productive relationships with external business partners and consultants.

- Developed regulatory strategy and provided leadership for execution of investigational and marketing applications for Epanova, a complex mixture of omega-3 free fatty acids (animal-sourced product).
- Established and maintained aggressive project plan for NDA submission, engaging and managing internal and external resources for development of the marketing application and corporate quality system.
- Identified and selected external partner organizations, negotiating favorable contracts for NDA execution.
- Liaison with regulatory agencies on all matters relating to drug development and compliance, including

Special Protocol Assessment meeting and Pre-NDA meeting.

**ETHICON INC (A JOHNSON & JOHNSON COMPANY), SOMERVILLE, NJ**

2010-2011

*Vice President, Regulatory Affairs*

Established vision, strategy and goals for the global Regulatory Affairs function aligned with the business unit and franchise needs as a member of the J&J Wound Management Board. Assured high performing global regulatory organization and project alignment with business goals for plasma-derived biologics, immunotherapy products, biologic/device combination products and medical devices.

- Led J&J Wound Management regulatory departments in US, EU and Israel (25+ professionals).
- Directed regulatory strategy, execution and planning of regulatory submissions for biosurgery products to achieve and maintain clinical trial authorizations and marketing approvals globally, directly or through J&J affiliates to help drive the growth of the J&J Wound Management Business.
- Led regulatory meetings with FDA, EU National CAs and Israeli Ministry of Health, including Pre-Submission meetings and regulatory aspects of Pre-Licensing Inspection and issue resolution meetings.
- Integrated and aligned Regulatory Affairs organizational structure, systems and processes across all sites to ensure global consistency and improved efficiency.
- Submissions and/or approvals included Evarrest BLA, MAA and Pediatric Investigational Plan, Thrombin Pad dossier, and approvals globally of Evicel, SurgiFlo with Thrombin (US BLA/PMA & EU).

**IMCLONE SYSTEMS INC, BRIDGEWATER, NJ**

2009 – 2010

*A wholly-owned subsidiary of Eli Lilly and Company*

*Sr VP, Global Regulatory Affairs and Drug Safety (Interim)*

*Vice President, Regulatory Affairs – Late Development*

Provided strategic direction and leadership for global regulatory and drug safety (80+ professionals) as the functional department head and member of the ImClone Management Committee.

- Formulated novel strategies and directed development, implementation and execution of global regulatory strategies for the successful conduct of Phase II and Phase III studies for monoclonal antibody development pipeline oncology projects (5 Phase III studies in 2009, 6 Phase III studies in 2010) including cixutumumab, necitumumab, ramudrumab, EB10 and IMC-18F1.
- Directed activities of the Regulatory Affairs global strategy leads and developed talent to ensure consistent and informative strategic support to business partners. Led key interactions and negotiations, and directed all interactions with health authorities for late stage development assets including Pre-IND, End of Phase 2 and protocol advice meetings.
- Developed and implemented new global regulatory operating model in alignment with key stakeholder needs and corporate business unit restructure to leverage talent and best practices.

**GPC BIOTECH INC, PRINCETON, NJ**

2006 – 2009

*Vice President, Worldwide Regulatory Affairs and Quality Compliance*

Provided leadership for global Regulatory in all aspects of strategy, preparation and management of regulatory submissions. Developed regulatory strategies and operational plans for investigational oncology drug products in alignment with commercial and development plans as a member of the leadership and development teams.

- Directed strategy and execution of NDA for satraplatin from planning and submission through regulatory review. Provided regulatory support to partner organization for MAA submission and review process.
- Defined strategy and directed execution of CTA and IND submissions for other NME oncology products.
- Regulatory support for FDA Oncologic Drugs Advisory Committee meeting preparation.
- Led meetings with the regulatory authorities for pre-NDA, pre-IND, multiple Type A meetings and PAI in the US, and supported CHMP Scientific Advice and Pre-Submission meetings in the EU.
- Provided regulatory oversight of label development, promotional material review, public disclosures, corporate communications and filings, etc.
- Assessed regulatory risks and probabilities of regulatory success for licensing opportunities.
- Led and developed Quality Assurance and Document Control functions to establish compliant and efficient Quality Systems. Ensured successful Pre-Approval Inspection with no observations.

**BRISTOL-MYERS SQUIBB, LAWRENCEVILLE, NJ**

2001 - 2006

*Vice President, Global Regulatory Operations**Vice President, Global Regulatory Sciences - CMC**Senior Director, Scientific Affairs*

Directed and developed a team of 40+ regulatory professionals responsible for the strategy, preparation and project management of global Chemistry, Manufacturing and Controls (CMC) submissions to secure and maintain regulatory approvals for investigational and commercial pharmaceutical products.

- Provided strategic, technical and managerial leadership for CMC Regulatory and Scientific Affairs, including development of regulatory strategy, liaison with regulatory authorities and execution of submissions for the Pharmaceutical Research Institute and Technical Operations.
- Defined strategic direction for CMC registration activities for new molecular entities and biologics (selected examples include Orenzia (abatacept), Baraclade (entecavir), Reyataz (atazanavir), Abilify (aripiprazole), Sustiva (efavirenz)), and for the maintenance of products throughout their lifecycle.
- Designed, developed and implemented systems for improving efficiency of department operations, CMC submission preparation and approval.
- Established an integrated Operations function that facilitated and enabled improved operational performance of Global Regulatory Sciences by capturing, analyzing, and leveraging resource and performance management, staffing and financial information. Integrated new resource management and performance measurement capabilities for the division.

**AVENTIS, COLLEGEVILLE, PA**

1992 – 2000

Formerly: RHÔNE-POULENC RORER, COLLEGEVILLE, PA  
FISONS PHARMACEUTICALS, MANCHESTER, UK

*Director, Quality Assurance and Regulatory North America, Aventis Pharma, Collegeville, PA**Director, Regulatory Compliance - Americas & Asia/Pacific, Rhone-Poulenc, Collegeville, PA**Senior Regulatory Affairs Associate, Fisons Corp, Rochester, NY**Regulatory Officer, Fisons PLC, Manchester, England*

Defined strategic direction for Marketed Product Regulatory Affairs and QA in North America with focus on meeting evolving business needs and goals. Provided leadership for resolution of quality and regulatory issues from pre-launch through product lifecycle.

- Directed team of Regulatory Affairs professionals in the development of CMC regulatory strategy and post-approval submissions, and in the maintenance of over 60 NDAs and worldwide marketing authorizations, Drug Listing/Establishment Registrations, DEA registrations, State Licenses, etc.
- Reduced \$3.6 million operations budget by 25% while maintaining high quality customer service and improving regulatory compliance.
- Closed analytical laboratory 3 months ahead of schedule, achieving savings of \$450,000.
- Developed and implemented corporate systems/procedures for change control, recalls, post-approval NDA submission preparation, approval and tracking, and department operations.
- Conducted meetings with FDA Office of Compliance, District Office and Review Divisions. Primary interface with FDA District Offices and other federal agencies such as USDA, DEA.
- Chaired Corporate Recall Committee. Managed 12 drug product recalls and all associated FDA communication. Negotiated recall requirements, releases of FDA and USDA import detentions.
- Advised multidisciplinary teams on regulatory requirements and submission strategy for respiratory, oncology, cardiovascular and anti-infective products. Represented company at successful FDA meetings and site inspections.

**PROFESSIONAL CERTIFICATIONS/ASSOCIATIONS**

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Regulatory Affairs Certified (RAC), 2001

Regulatory Affairs Professional Society: Member since 1996

Drug Track Chair, RAPS Program Advisory Committee, 2005

Distinguished Alumni Award, School of Biomedical Sciences, UMDNJ, 2003

National Lipid Association: Member since 2011

National Association of Female Executives: Member since 2003

Industrial Advisory Board, Department of Biomedical Engineering, UMDNJ: Member since 2001



## **PUBLICATIONS/PRESENTATIONS**

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2005 Regulatory Affairs Professional Society Annual Conference. Drugs Track Chair and Moderator  
CDER Update. Member: RAPS Program Advisory Committee

Lloyd, R. M. 1999. The Drug Approval Process. Licensing Executive Society/Association of University  
Technology Managers, Philadelphia, PA.

Shatkin, A.J., Lloyd, R.M., and Tillotson, L.E. 1993. "Translation regulation by reovirus structural  
proteins" In: Regulation of Gene Expression in Animal Viruses. Plenum Press, N.Y. 151-162.

Lloyd, R.M. and Shatkin, A.J. 1992. Translational stimulation by reovirus polypeptide  $\sigma 3$ : Substitution for  
VAI RNA and inhibition of phosphorylation of the  $\alpha$  subunit of eukaryotic initiation factor 2. *J Virol.* 66  
(12): 6878-6884.

Lloyd, R.M. 1992. Molecular Mechanism of Translational Control Mediated by the Reovirus S4 Gene.  
Ph.D. Thesis. Rutgers University, New Brunswick, N.J.

Lloyd, R.M. and Shatkin, A.J. 1992. Translational control in cells expressing the reovirus S4 gene. 11th  
Annual American Society for Virology Meeting, Ithaca, N.Y.

Shatkin, A.J., Lloyd, R.M., and Tillotson, L.E. 1992. Regulation of reovirus gene expression. Intl.  
Workshop: The Regulation of Gene Expression by Animal Viruses, Mallorca, Spain.

Brandl, H. Gross, R., Lenz, R.W., Lloyd, R.M., and Fuller, R.C. 1991. The accumulation of poly (3-  
hydroxyalkanoates) in *Rhodobacter sphaeroides*. *Arch Microbiol.* 155:337-340.

Lloyd, R.M. and Shatkin, A.J. 1991. Role of the reovirus S4 gene in the regulation of translation. 10th  
Annual American Society for Virology Meeting, Fort Collins, Co.

Shatkin, A.J., Fajardo, E., Lloyd, R.M. and Tillotson, L.E. 1991. Translational controls in cells expressing  
reovirus genes. International Workshop on Virology, Madrid, Spain.

Shatkin, A.J., Fajardo, E., Lloyd, R.M. and Tillotson, L.E. 1991. Reovirus-mediated translational controls.  
Keystone Symposium on Translational Control, Tammarron, Co.

Lloyd, R.M. and Shatkin, A.J. 1990. Translational regulation in reovirus infected and transfected  
mammalian cells. 3rd Int. Symposium on Double-Stranded RNA Viruses, Kona, HI.

Lloyd, R.M., Giantini, M. and Shatkin, A.J. 1990. Translational control, DAI phosphorylation and the  
reovirus S4 gene. 9th Annual American Society for Virology Meeting, Salt Lake City, UT.

Lloyd, R.M., Giantini, M. and Shatkin, A.J. 1990. CAT mRNA translation is similarly stimulated by  
polypeptide  $\sigma 3$  of reovirus serotypes 1 and 3. American Society for Microbiology National Meeting,  
Anneheim, CA.

Fajardo, E., Lloyd, R.M., Seliger, L., Shatkin, A.J. and Tillotson, L.E. 1990. Reovirus gene expression in  
transfected mammalian cells. VII Intl. Congress on Virology, Berlin, Germany.

Giantini, M., Seliger, L., Lloyd, R.M. and Shatkin, A.J. 1989. Stimulation of CAT mRNA translation by  
reovirus polypeptide  $\sigma 3$  in co-transfected COS cells. 8th Annual American Society for Virology Meeting,  
London, Canada.

Brandl, H., Gross, R., Lloyd, R.M., Lenz, R. and Fuller, R.C. 1988. Biodegradable Thermoplastics: Novel  
poly- $\beta$ -hydroxy-alkanoates from *Rhodospirillum rubrum* and *Pseudomonas oleovorans*. American Society  
for Microbiology Annual Meeting.