



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Recommendations for Scientific Research & Prevention Program (SRPP) Committees

Scientific Review Council Ad Hoc Members

- Andrea Califano, Ph.D.
- X. Shirley Liu, Ph.D.

Product Development Research Peer Review Panels

- Michael Cheng, MD
- Arnab Ghosh, MD, PhD
- Mickey C-T. Hu, MS, PhD
- Rachel Humphrey, MD
- Walter Stadler, MD, FACP
- Neil Vasani, MD, PhD

BIOGRAPHICAL SKETCH

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

NAME: ANDREA CALIFANO

eRA COMMONS USER NAME: CALIFANOA

POSITION TITLE: Clyde and Helen Wu Professor of Chemical and Systems Biology, Departments of Systems Biology, Biochemistry & Molecular Biophysics, Biomedical Informatics, and Medicine

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE	Completion Date	FIELD OF STUDY
University of Florence, Italy	Equiv B.S.	05/1982	Physics
University of Florence, Italy	Laurea	04/1985	Physics
Istituto Nazionale di Ottica, Florence	Res. Assoc.	07/1986	Physics
Massachusetts Institute of Technology, MA	Post-doc	03/1986	Information Mechanics

A. Personal Statement

I am the Clyde and Helen Wu Professor of Chemical and Systems Biology and the founding Chair of the Department of Systems Biology at Columbia University. I was trained as a physicist and have applied physics-based approaches, including extensive use of information theory, to reverse engineering and interrogation of gene regulatory networks. I have pioneered use of mammalian networks as models for the quantitative analysis of cancer related phenotypes and for identification of driver genes, driver mutations, and small-molecule modulators of tumor vulnerabilities. In particular, I have demonstrated that (a) tumor specific transcriptional and signaling networks can be inferred accurately using information theoretic principles from large collections of molecular profile data of patient-derived tumor samples, using algorithms developed by my lab such as ARACNe[4 – 7]; (b) these networks can be interrogated using tumor derived signatures to discover master regulators (MRs) of tumor progression and drug sensitivity[8 – 11]; (c) computational analysis of *de novo* inferred networks, upstream of such MRs, can systematically elucidate the repertoire of genetic alterations and germline variants responsible for aberrant disease activity[12 –13]. Finally, (d) my lab has shown that inhibition of MRs using individual compounds or synergistic compound combinations, as computationally inferred from perturbational signatures, can abrogate tumor viability *in vitro* and *in vivo* [14 –17]. Since MR analysis can be performed on an individual gene expression profiles, this methodological approach is uniquely suited to the dissection of tumor mechanism heterogeneity, either from individual patient samples or even from single cells. Together, these methodologies represent one of the most extensive and validated toolkits for the systems biology based elucidation of novel cancer targets, small-molecule inhibitors, and biomarkers, having resulted in significant translation. Discoveries supported by these approaches have been used as a rationale for several clinical studies, including use of combination therapy in relapsed HER2+ following trastuzumab therapy (NCT02066532), in metastatic breast cancer (NCT02632071), and in several N of 1 studies, where MR-based tumor vulnerabilities are identified and targeted pharmacologically on an individual patient. They are thus poised to provide valuable and complementary approaches to current mutational bases approaches.

B. Positions and Honors

1986 – 1993 Research Staff member, Exploratory Computer Vision Group, IBM TJ Watson Research Center
 1993 – 1997 Manager, Computational Biology Group, IBM TJ Watson Research Center
 1997 – 2000 Program Director, IBM Computational Biology Center
 1997 – 2007 Fellow of the Institute of Electrical and Electronic Engineers (IEEE)
 2000 – 2003 Founder, EVP and Chief Technology Officer, First Genetic Trust, Inc.
 2003 – pres. Professor of Biomedical Informatics, Columbia University

- 2005 – pres. Fellow of the New York Academy of Sciences
- 2005 – 2019 Assoc. Director for Bioinformatics, Herbert Irving Cancer Center, Columbia University
- 2005 – 2017 Director, Center for the Multiscale Analysis of Genomic Networks (MAGNet)
- 2005 – pres. Co-Director, Center for Computational Biology and Bioinformatics (C2B2)
- 2008 – 2016 Member, Board of Scientific Advisors, National Cancer Institute
- 2008 – pres. Fellow of the New York Academy of Medicine
- 2009 – 2013 Founding Director of the Systems Biology Initiative, Columbia University
- 2010 – pres. Director, JP Sulzberger Columbia Genome Center, Columbia University
- 2012 – pres. Clyde and Helen Wu Professor of Chemical and Systems Biology, Columbia University
- 2013 – pres. Founding Chairman of the Department of Systems Biology, Columbia University
- 2014 – pres. Member, SAB, Koch Cancer Center, MIT
- 2014 – pres. Scientific Editor, Cancer Discovery and Cell Systems
- 2015 – pres. NCI Outstanding Investigator Award
- 2015 – pres. Fellow, American Association for the Advancement of Science
- 2015 – pres. Cofounder and Chief Scientific Advisor, DarwinHealth, Inc.
- 2017 – pres. Fellow of the International Society of Computational Biology
- 2017 – pres. Chair, Columbia Committee for Precision Cancer Medicine
- 2017 – pres. The Pershing Square Foundation, Scientific Review Council
- 2018 – pres. Member, National Academy of Medicine
- 2018 – pres. Advisor, Frederick National Laboratory Advisory Committee (FNLAC)

C. Contributions to Science (* indicates co-Sr. authorship)

Functional Characterization of Mutations Using Network-based Inference of Protein Activity: Identifying oncoproteins whose dysregulated activity is necessary for tumor maintenance on an individual patient basis is crucial for developing personalized treatment plans. However, this is challenging as genetic alterations are only partially predictive and there are no direct assays to measure protein activity. To address this problem, the Califano lab recently published the *Virtual Proteomics by Enriched Regulon analysis* (VIPER) algorithm [1]. VIPER computes a highly accurate measurement of protein activity, on an individual sample basis, from the expression of their transcriptional targets (*regulon*). VIPER is uniquely suited for the identification of novel cancer targets, to functionalize genomic alterations of unknown relevance, and to assess compound activity on the full repertoire of regulatory proteins in a cancer cell. It has helped elucidate MR proteins in several human malignancies, from leukemia, and lymphoma, to prostate cancer, breast cancer, and glioma [2]. It has also been extended to single cell analysis, where it solves the gene-dropout problem caused by low sequencing depth [3].

1. Alvarez MJ, Shen Y, Giorgi FM, Lachmann A, Ding BB, Ye BH, **Califano A**. Functional characterization of somatic mutations in cancer using network-based inference of protein activity. *Nat Genet.* 2016 Aug;48(8):838-47. PMID: PMC5040167.
2. **Califano A**, Alvarez MJ. The recurrent architecture of tumour initiation, progression and drug sensitivity. *Nat Rev Cancer.* 2017 Feb;17(2):116-130. Review. PMID: PMC5541669.
3. Ding H, Douglass EF Jr, ... , **Califano A**. Quantitative assessment of protein activity in orphan tissues and single cells using the metaVIPER algorithm. *Nat Commun.* 2018 Apr; 9(1), 1471. PMID: PMC5902599.

Reverse Engineering of Mammalian Regulatory and Signaling Networks (interactomes): The Califano lab has pioneered use of information theoretic and Bayesian methods to reverse engineer genome-wide, tissue-specific regulatory network (interactomes), including (a) the first transcriptional network of a human cell reconstructed by the ARACNe algorithm [4]; (b) the first network representing post-translational modulators of transcription factor activity in human cells, using the MINDy algorithm [5]; (c) the first protein-protein interaction network based on 3D protein structure information, using the PrePPI algorithm [6]; and (d) a novel regulatory layer implemented by competitive endogenous RNA species, using the Hermes and Cupid algorithms [7]. These algorithms have shown accuracy and sensitivity comparable—and often exceeding—those of medium and high-throughput experimental assays.

4. Basso K, ..., **Califano A**. Reverse engineering of regulatory networks in human B cells. *Nat Genet.* 2005;37(4):382-90. PMID: 15778709.
5. Wang K, ..., **Califano A**. Genome-wide identification of post-translational modulators of transcription factor activity in human B cells. *Nat Biotechnol.* 2009;27(9):829-39. PMID: PMC2753889.
6. Zhang QC, ..., **Califano A***, **Honig B***. Structure-based prediction of protein-protein interactions on a genome-wide scale. *Nature.* 2012;490(7421):556-60. PMID: PMC3482288.

7. Sumazin P, ..., **Califano A**. An extensive microRNA-mediated network of RNA-RNA interactions regulates established oncogenic pathways in glioblastoma. *Cell*. 2011;147(2):370-81. PMID: PMC3214599.

Elucidation of Master Regulators of Tumor-related Phenotypes: The Califano lab has developed algorithms for the quantitative interrogation of tissue-specific interactomes, using signatures representing phenotypic transition between two states (e.g., primary vs. metastatic cancer). The Master Regulator (MR) Inference algorithm (MARINa) and its most recent extension (VIPER), in particular, have been instrumental in elucidating MR proteins that mechanistically implement tumor cell state. For instance, they were used to elucidate CEBPB and STAT3 as synergistic MRs of the mesenchymal subtype of human glioma [8]. In collaboration with Dr. Adolfo Ferrando, MARINa helped elucidate MR proteins effecting glucocorticoid resistance in T-cell acute lymphoblastic leukemia [9]. Similarly, application to prostate cancer was instrumental in elucidating FOXM1 and CENPF as synergistic MRs of aggressive/metastatic prostate cancer [10], while analysis of two independent neuroblastoma cohorts identified a 10-protein MR module controlled by a TEAD4-MYCN positive feedback loop as the key mechanistic driver of a subtype of the disease associated with poor prognosis [11].

8. Carro MS, ..., **Califano A***, Iavarone A*. The transcriptional network for mesenchymal transformation of brain tumours. *Nature*. 2010;463(7279):318-25. PMID: PMC4011561.
9. Piovani E, ..., **Califano A***, Ferrando A*. Direct reversal of glucocorticoid resistance by AKT inhibition in acute lymphoblastic leukemia. *Cancer Cell*. 2013;24(6):766-76. PMID: PMC3878658.
10. Aytes A, ..., **Califano A***, Abate-Shen C*. Cross-species analysis of genome-wide regulatory networks identifies a synergistic interaction between FOXM1 and CENPF that drives prostate cancer malignancy. *Cancer Cell*. 2014;25(5):638-51. PMID: PMC4051317.
11. Rajbhandari P, ..., **Califano A**. Cross-cohort analysis identifies a TEAD4 ↔ MYCN positive-feedback loop as the core regulatory element of high-risk neuroblastoma. *Cancer Discovery*. 2018 May;8(5):582-599. PMID: PMC5967627

Network-based Identification of Driver Mutations: Tumor initiation, progression, and drug sensitivity are determined by a large, diverse repertoire of genetic alterations and germline variants, which differ between tumors and even between cells within a tumor. Yet, analysis of large cancer genome databases reveals that only a small fraction of tumors is characterized by two or more recurrent genetic alterations. This suggests that most cancer mutations may represent rare or even private events. The Califano lab proposed that MR proteins implement regulatory bottlenecks that integrate the effect of complex genetic alteration patterns to implement the key genetic programs necessary for tumor cell state maintenance (i.e., tumor bottleneck hypothesis) [12]. This approach led to discovery of novel mutational events that were experimentally validated as causal in lymphomagenesis and gliomagenesis. For instance, network-based analysis of mesenchymal glioma samples identified only two alterations—the homozygous deletion of the E3 culling ligase adapter protein KLHL9 (in ~60% of subtype) and the focal amplification of the CEBPD developmental transcription factor (in ~30% of subtype) [13]. Experimental validation showed that KLHL9 is necessary for E3 Cullin-mediated ubiquitylation of both CEBPB and CEBPD (two previously validated MRs of mesenchymal glioma) and for their proteasomal degradation, and that rescue of KLHL9 expression in homozygously deleted mesenchymal patient derived xenografts abrogated tumor viability *in vivo*. The same approach was used to discover novel variants and mutations in Alzheimer's and Breast Cancer.

12. **Califano A**, Alvarez MJ. The recurrent architecture of tumour initiation, progression and drug sensitivity. *Nat Rev Cancer*. 2017;17(2):116-30. PubMed PMID: 27977008. PMID: PMC5541669.
13. Chen JC, ..., **Califano A**. Identification of causal genetic drivers of human disease through systems-level analysis of regulatory networks. *Cell*. 2014;159(2):402-14. PMID: PMC4194029.

Systematic Identification of Small Molecule Inhibitors of Master Regulator Activity: We hypothesized that analysis of gene expression profiles following compound perturbation in cells representative of a specific tumor subtype, using MARINa, can elucidate a compound's functional effectors and potential targets (both inhibited and activated). More importantly, compounds whose effectors match the MR profile of a tumor subtype (i.e. inhibit positive MRs and activate negative MRs) should induce critical loss of tumor viability. Finally, compounds with complementary effect in inverting a tumor MR pattern (e.g., where each compound inverts a non-overlapping component of the overall MR pattern) should elicit significant synergy [14]. We validated this approach using a large dataset of profiles of DLBCL cells. We then developed the SynGEN algorithm to identify synergistic compounds based on analysis of overlap of individual MARINa MR signatures [15]. Following SynGEN ranking of all compound pairs (91 in total) by predicted synergy, we experimentally validated their synergistic interaction in LY3 cells. Remarkably, SynGEN predicted 50% of true synergistic pairs at 5% false discovery rate (FDR). The

ability to match drugs to individual patients based on their computationally inferred ability to invert the activity of the top MR proteins controlling tumor state was recently demonstrated in the context of gastroenteropancreatic neuroendocrine tumors, leading to NY CLIA certification of two RNA-based tests (OncoTarget and OncoTreat) [16]. There are currently several clinical and pre-clinical trials that are enrolling patients based on the availability of these MR-based methodologies, including (a) a phase 2 trial to test the combination of trastuzumab and ruxolitinib in HER2+ relapsed breast cancer patients, (b) a SWOG study to identify VIPER-inferred pharmacologically-actionable dependencies in breast cancer patients with significant residual tumor, following neoadjuvant chemotherapy (c) the Columbia N of 1 study where patients representing 14 malignancies who had progressed on 3 to 7 lines of therapy are being transplanted in PDX models, which are then treated with drugs predicted by OncoTreat and OncoTarget (d) a PCF-funded challenge award for an N of 1 in metastatic CRPC (e) a phase 2 trial of entinostat in gastroenteropancreatic neuroendocrine tumors and (f) a Lustgarten-foundation funder N of 1 trial in pancreatic cancer. These studies also led to the development of novel methodologies for elucidating drug mechanism of action from compound-mediated perturbational profiles, such as DeMAND [17].

14. Mitrofanova A, ..., Abate-Shen C*, **Califano A***. Predicting drug response in human prostate cancer from preclinical analysis of in vivo mouse models. *Cell Reports*. 2015;12:1-12. PMID: PMC4591242.
15. Bansal M, ..., Stolovitzky G*, **Califano A***. Predicting compound synergy from first principles, a crowdsourcing approach. *Nat Biotech*. 2014;32(12):1213-22. PMID: PMC4399794.
16. Alvarez MJ, ..., Modlin I*, **Califano A***. A precision oncology approach to the pharmacological targeting of mechanistic dependencies in neuroendocrine tumors. *Nat Genet*. 2018 Jul;50(7):979-989. PMID: 29915428.
17. Woo JH, ..., **Califano A**. Elucidating compound mechanism of action by network dysregulation analysis in perturbed cells. *Cell*. 2015;162:441-451. PMID: PMC4506491.

A full list of publications can be found at:

<http://www.ncbi.nlm.nih.gov/sites/myncbi/andrea.califano.1/bibliography/43566462/public/?sort=date&direction=descending>

D. Research Support

Selected Ongoing Research Support

NIH 1 U01 CA217858-03

Califano (PI)

08/01/17 - 07/31/22

Systematic Identification and Pharmacological Targeting of Tumor Dependencies for Precision Cancer Medicine

To develop the first mechanistic approach for precision cancer medicine, where therapeutic targets, associated inhibitors, and population stratification biomarkers are systematically derived from precise, mechanistic understanding of tumor state regulation and of its drug-induced modulation.

NIH 1 R35 CA197745-05

Califano (PI)

08/14/15 - 07/31/22

Outstanding Investigator Award: Elucidating the dependencies of tumor initiating and drug-resistant niches in human malignancies by genome-wide molecular profiling of single cells

To develop a novel methodological framework integrating both experimental and computational approaches to study the impact of tumor heterogeneity on progression and drug resistance at the single cell level.

NIH 1 U54 CA209997-04

Califano (PI)

08/08/16 - 07/31/21

Centers for Cancer Systems Therapeutics (CaST)

To leverage proven methodologies and novel and integrative systems biology approaches to foster a highly innovative framework for the rapid, patient-centric prioritization and evaluation of cancer therapeutic strategies targeting target tumor homeostasis, including single agent and combination therapy.

NCI 3 P30 CA13696-45

(Rustgi)

07/01/14 - 06/30/20

Cancer Center Support Grant

To support the leadership of Columbia University's lab, clinical and population-based cancer research programs and the shared resources serving the University's Cancer Center members.

Role: Director

NIH 5R01HD085904-03

(Shen)

07/10/16 - 04/30/21

NIH/NICHD

Systems analysis of mouse gastrulation The specific aims in this project are: 1) identification of master regulators of mouse epiblast during gastrulation, 2) analysis of the transcriptional network that regulates mouse gastrulation, and 3) functional analyses of the regulatory network for gastrulation.

Role: Investigator

Foundation Grant

Price Family Foundation (Johannessen) 08/01/17 – 07/31/21

A research collaboration underway between Columbia's Department of Systems Biology, the Broad Institute of MIT and Harvard and Columbia Medical Center is working to accelerate the discovery of new cancer drug combinations targeted at esophageal cancer.

Role: Principal Investigator (Subaward)

Lustgarten Foundation (Olive, Califano) 04/01/18 – 03/31/21

Clinical translation of regulatory network-based precision medicine for pancreatic cancer The Lustgarten Foundation has awarded a three-year grant, as part of its Translational Clinical Program, to test a new precision medicine approach to the treatment of metastatic pancreatic cancer.

Role: Co-PI

Hyundai Hope on Wheels (Yamashiro) (Califano) 05/01/18-04/30/23

Hyundai Hope on Wheels

Targeting Master Regulator Dependencies in High-Risk Osteosarcoma (OS)

We propose to use computational biology strategies to elucidate universal tumor dependencies that will not only help prioritize therapy for the individual patient, but also maximize the opportunity to innovate treatment for the disease as a whole.

Role: Co-Investigator

Selected Completed Research Support

NIH R01 CA193837-05 (Sawyers) 04/01/15 - 03/31/20

Defining the Role of ERG in Modulating the AR Cistome and Antiandrogen Sensitivity

To analyze RNA-Seq data generated by the Sawyers group to identify critical regulators within the interaction network between PTEN, ERG, and AR.

Role: Principal Investigator (Subaward)

NCI/CTDD U01 CA168426-04 Califano (PI) 06/01/12 - 04/30/17

Systems Biology of Tumor Progression and Drug Resistance

To build a successful pipeline for the discovery and validation of master regulator modules that implement functional bottlenecks that integrate aberrant signals from multiple alterations, thus constituting actionable tumor dependencies.

NIH 5 U54 CA121852 Califano (PI) 09/26/05 - 07/31/16

National Center for the Multi-Scale Analysis of Genomic and Cellular Networks (MAGNet)

To build a National Center for Biomedical Computing providing advanced algorithms and databases for Cellular Networks.

Leidos 15x36-269 Califano (PI) 02/01/15 - 01/31/17

Integrative Analysis of Genomic and Proteomic data from The Cancer Genome Atlas

To jointly analyze TCGA data, using interactome-based, integrative algorithms, to coherently reorganize our knowledge of cancer around MR genes representing mechanistic tumor dependencies and their upstream genomic determinants, on an individual patient basis.

Chan Zuckerberg Initiative (Califano) 02/01/18 - 08/31/19

Assembly of context-specific gene regulatory networks for the systematic reconstruction of single-cell states and their molecular determinants

The goal is to complement the individual cell states identified by our analysis with an Atlas of matched, single-cell derived interactomes, eventually extending to all Human Cell Atlas entries. These will support key analyses, including identification of lineage markers and reprogramming factors.

Role: Principal Investigator

BIOGRAPHICAL SKETCH

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

NAME: Liu, Xiaole Shirley

eRA COMMONS USER NAME (credential, e.g., agency login): SHIRLEY_LIU

POSITION TITLE: Professor of Biostatistics and Computational Biology

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

INSTITUTION AND LOCATION	DEGREE (if applicable)	Completion Date MM/YYYY	FIELD OF STUDY
Peking University, Beijing, China		07/1994	Biochemistry
Smith College, Northampton, MA	B.A./B.A.	05/1997	Biochemistry/Computer Science
Stanford University, Stanford, CA	Ph.D./Ph.D. minor	06/2002	Biomedical Informatics/Computer Science
Harvard School of Public Health, Dana-Farber Cancer Institute	Research Fellow	06/2003	Biostatistics and Computational Biology

A. Personal Statement

I am a **computational and systems biologist in cancer research**, with expertise in **algorithm development, data integration, cancer gene regulation, and precision cancer medicine**. I am an associate member at the Broad Institute, and the co-director (with Myles Brown) of the Center for Functional Cancer Epigenetics at the Dana-Farber Cancer Institute. I am a member of the mod/ENCODE consortia (NHGRI) and Information Technology for Cancer Research initiative (NCI), and the principal investigator of the Cancer Immunologic Data Commons as part of the NCI Cancer Moonshot project on cancer immunotherapy. My group **developed many widely used and cited algorithms** for transcription factor (TF) motif finding (5), ChIP-chip (6) / ChIP-seq (7, 8), MNase (10) / DNase-seq (12), CRISPR screen (17, 19), immune repertoire (22, 24), and scRNA-seq/scATAC-seq (MAESTRO) data analysis. Through integrating genome-wide transcription factor binding, chromatin dynamics, and gene expression profiles, we modeled the specificity and function of transcription factors (3, 13, 14, 16), chromatin regulators (11) and lncRNAs (Du et al, NMSB 2013; Du et al Nat Comm 2016) in tumor development and progression. We have a long-standing interest and track record in **big data integration and bias correction in genomics**, being at the forefront of identifying and correcting biases in microarray and next-generation sequencing data to facilitate better integration (1, 2, 12). We conducted the first comprehensive integrative analyses to annotate the *C. elegans* genome (modENCODE, Science 2010; Nature 2014), were among the earliest to integrate epigenetic profiles with GWAS (Ahmadiyeh et al, PNAS 2010) and QTL (Trynka et al, Nat Genet 2013) studies, and were the pioneers to integrate ENCODE and TCGA data (3). Recently my group is transitioning into translational aspects of cancer genomics, by integrating large-scale public data to understand the mechanism of action and predict response to **targeted and immunotherapies** (4, 21-24). I have an **H-index of 94** and published over 60 papers in Nature, Science, or Cell series journals. I have a total citation over 40K according to Google Scholar statistics, and was rated as a 2019 Highly Cited Author by Web of Science. Since becoming a faculty in 2003, I have successfully **mentored eighteen trainees to start tenure track faculty positions**, including 1 K22 and 3 K99 awardees, 1 Damon Runyon Fellow, 3 Texas CPRIT scholars, and 1 NIH Earl Stadtman Investigator.

- Jiang P, Freedman ML, Liu JS, Liu XS (2015). Inference of transcriptional regulation in cancers. *Proc Natl Acad Sci U S A* 112(25):7731-6. PMID: PMC4485084.

2. Meyer CA*, Liu XS* (2014). Identifying and mitigating bias in next-generation sequencing methods for chromatin biology. *Nat Rev Genet* 15(11):709-21. PMID: PMC4473780.
3. Chen C, Zheng R, Tokheim C, Dong X, Fan J, Wan C, Tang Q, Brown M, Liu JS, Meyer C*, Liu XS* (2020). Determinants of transcription factor regulatory range. *Nat Commun.* 11:2472. PMID: PMC7235260
4. Applications of immunogenomics to cancer. Liu XS* and Mardis ER* (2017). *Cell.* 168(4):600-612.

B. Positions and Honors

Positions and Employment

2002–2003	Independent Research Fellow, Department of Biostatistics, Harvard School of Public Health, Dana-Farber Cancer Institute
2003–2007	Assistant Professor, Department of Biostatistics and Computational Biology, Dana-Farber Cancer Institute, Harvard School of Public Health
2008-2012	Associate Professor, Department of Biostatistics and Computational Biology, Dana-Farber Cancer Institute, Harvard School of Public Health
2009-2019	Visiting Professor, Department of Bioinformatics, Tongji University, Shanghai, China
2011-present	Associate Member, Broad Institute of MIT and Harvard
2011-present	Co-director, Center for Functional Cancer Epigenetics, Dana-Farber Cancer Institute
2012-present	Professor of Biostatistics and Computational Biology, Department of Data Science, Dana-Farber Cancer Institute, Harvard T.H. Chan School of Public Health
2013-2019	Visiting professor, Tongji University Affiliated Shanghai Pulmonary Hospital, Shanghai, China
2015-present	Professor of Statistics, Harvard University

Other Experiences

2001	Conference Chair, Biomedical Computation at Stanford (BCATS2001)
2003	Conference Organizer, Workshop Chair, Symposium on Computational Biology, Harvard University, Radcliffe Institute for Advanced Study
2005-present	Steering Committee, International Bioinformatics Workshop
2012-2018	Scientific advisory board at the Chinese Academy of Science-Max Plank Society Partner Institute for Computational Biology
2014-present	Organizer, Cold Spring Harbor Asia meeting in Systems Biology of Gene Regulation and Genome Editing
2017	Chair, Gordon Research Conference on Cancer Genetics and Epigenetics
2018, 2020	AACR Annual Meeting Program Committee
Editorial Board for:	Genomics (2006-2008), BMC Bioinformatics (2010-2014), Biostatistics (2010-2014), Annals of Applied Statistics (2010-2014), Genome Biol (2011-), Quantitative Biology (2012-), Molecular Cancer Research (2014-), Genome Research (2014-), Nucleic Acids Research (2016-2019), Cell systems (2019-), Genomics, Proteomics, and Bioinformatics (2020-)
Reviewer for:	<u>Grants</u> : National Institute of Health (GCAT regular member 2011-2017, chair 2015-2017; NCI Integrative Cancer Biology Program 2004; GCAT 2009; GGG 2010; GGG chair 2019)

Honors and Awards

1997	<i>summa cum laude</i> , Highest Departmental Honors in Biochemistry, <i>Sigma Xi, Phi Beta Kappa</i> , Smith College
1997-2000	Lucille P. Markey Biomedical Research Predoctoral Fellowship, Stanford University
2005, 2014	Claudia Adams Barr Award for Innovative Basic Cancer Research, Dana-Farber Cancer Institute
2008-2010	Alfred P. Sloan Research Fellowship
2013-2019	The National Distinguished Expert (type B), Thousand Talent Program, China
2014	Claire W. and Richard P. Morse Research Award
2016	Richard E Weitzman Outstanding Early Career Investigator Award, Endocrinology Society
2017-present	Breast Cancer Research Foundation Investigator
2019	Fellow, International Society of Computational Biology
2020	Innovator Award, International Society of Computational Biology
2021	Benjamin Franklin Award for Open Access in the Life Sciences, Bioinformatics.org

C. Contribution to Science

Complete bibliography: <https://www.ncbi.nlm.nih.gov/myncbi/xiaole.liu.1/bibliography/public/>

Google Scholar profile: <https://scholar.google.com/citations?user=8XNfVucAAAAJ&hl=en>

Selected from over 200; *Co-corresponding authors.

- I. **ChIP-chip / seq data analysis.** We are the pioneers in algorithm development for ChIP-chip (6), ChIP-seq (7) peak calling, downstream motif (5) and integrative (8) analyses. These four algorithms were **cited by over 10K with a user base of over 10K**. Liu Lab also recently published a computational pipeline for the integrative analysis of scRNA-seq and scATAC-seq (MAESTRO, Wang et al, Genome Biol 2020).
 5. **Liu XS**, Brutlag DL, Liu JS (2002). An algorithm for finding protein-DNA binding sites with applications to chromatin immunoprecipitation microarray experiments. *Nat Biotechnol.* 20(8):835-9.
 6. Johnson WE, Li W, Meyer CA, Gottardo R, Carroll JS, Brown M, **Liu XS** (2006). MAT: Model-based Analysis of Tiling-arrays for ChIP-chip. *Proc Natl Acad Sci U S A.* 103(33): 12457-62. PMID:PMC1567901.
 7. Zhang Y, Liu T, Meyer CA, Eeckhoute J, Johnson DS, Bernstein B, Nusbaum C, Myers RM, Brown M, Li W*, **Liu XS*** (2008). Model-based analysis of ChIP-Seq (MACS). *Genome Biol.* 9(9):R137. PMID:PMC2592715.
 8. Liu T, Ortiz JA, Taing L, Meyer CA, Lee B, Zhang Y, Gene Shin HG, Wong SS, Ma J, Lei Y, Pape UJ, Poidinger M, Chen Y, Yeung K, Brown M, Turpaz Y*, **Liu XS*** (2011). Cistrome: an integrative platform for transcriptional regulation studies. *Genome Biol.* 12(8):R83. PMID:PMC3245621.
- II. **Epigenetics and chromatin.** We are pioneers to use the dynamics of nucleosomes (10) and chromatin accessibility profiles (12; He et al, Genome Res, 2012) to predict transcription factor binding changes during a biological process. We generated the first high throughput nucleosome map in the human genome (9), and are the first to report the functional switch of EZH2 from a polycomb repressor to a transcriptional co-activator (11) in cancers. Through ChIP-chip/seq and MNase-seq, we identified the epigenetic signatures that are associated with embryonic pluripotency and zygotic genome activation (Vastenhouw et al, Nat 2010; Zhang et al, Genome Res 2014).
 9. Oszolak F, Song JS, **Liu XS***, Fisher DE* (2007). Global chromatin structure mapping of human promoters. *Nat Biotechnol.* 25(2):244-8.
 10. He HH, Meyer C, Shin H, Bailey S, Wei G, Wang Q, Zhang Y, Xu K, Ni M, Lupien M, Mieczkowski P, Lieb JD, Zhao K, Brown M*, **Liu XS*** (2010). Nucleosome dynamics defines transcriptional enhancers. *Nat Genet.* 42(4):343-7. PMID:PMC2932437.
 11. Xu K, Wu ZJ, Groner AC, He HH, Cai C, Lis RT, Wu X, Stack EC, Loda M, Liu T, Liu T, Xu H, Cato L, Thornton JE, Gregory RI, Morrissey M, Vessella RL, Montironi R, Magi-Galluzzi C, Kantoff PW, Balk SP, **Liu XS***, Brown M* (2012). EZH2 Oncogenic activity in castration resistant prostate cancer is polycomb-independent. *Science.* 338(6113):1465-9. PMID:PMC3625962.
 12. He HH, Meyer CA, Hu SS, Chen MW, Zang C, Liu Y, Rao PK, Fei T, Xu H, Long H*, **Liu XS***, Brown M* (2014). Refined DNase-seq protocol and data analysis reveals intrinsic bias in transcription factor footprint identification. *Nat Methods* 11(1):73-8. PMID:PMC4018771.
- III. **Nuclear receptor function:** We were among the earliest pioneers to use ChIP-chip and later ChIP-seq to investigate the genome-wide binding, target genes, interacting factors, and function of nuclear receptors. We are the first to conduct genome-wide ChIP-chip study of enhancer-binding transcription factors in mammalian system (13) and discovered FoxA1 as the pioneering factor for estrogen receptor (Carroll et al, Cell 2005; Lupien et al, Cell 2008). Our work advanced the mechanistic understanding of nuclear receptor function in cancers (13, 14, 16), metabolic syndromes (15) and other physiological processes (Tang et al, Cancer Res 2011). Due to these contributions, I received the Endocrinology Society Richard E. Weitzman Award in 2016.
 13. Carroll JS, Meyer CA, Song J, Li W, Brodsky AS, Hall G, Geistlinger TR, Eeckhoute J, Wang QB, Bekiranov S, Sementchenko V, Fox EA, Silver PA, Gingeras TR, **Liu XS***, Brown M* (2006). Genome wide analysis of estrogen receptor binding sites. *Nat Genet.* 38(11):1289-97.
 14. Wang Q, Li W, Zhang Y, Yuan X, Beroukhim R, Wang H, Lupien M, Wu T, Regan MM, Meyer CA, Carroll JS, Manrai AK, Jänne OA, Balk SP, Mehra R, Chinnaiyan AM, Rubin MA, True L, Giorentino M, Fiore C, Loda M, Kantoff PW, **Liu XS***, Brown M* (2009). Androgen receptor regulates a distinct

transcription program in androgen-independent prostate cancer. *Cell*. 138(2):245-56.
PMCID:PMC2726827

15. Feng D, Liu T, Sun Z, Bugge A, Mullican SE, Liu XS, Lazar MA (2011). A circadian rhythm orchestrated by histone deacetylase 3 controls hepatic lipid metabolism. *Science*. 331(6022):1315-9. PMCID:PMC3389392
16. Ni M, Chen Y, Bailey ST, Imai Y, Liu XS*, Brown M* (2011). Targeting androgen receptor in estrogen receptor-negative breast cancer. *Cancer Cell*. 20(1):119-31. PMCID:PMC3180861

IV. CRISPR screens: CRISPR screen is a powerful technique for systematic genetic analysis to identify key genes for tumorigenesis and progression, biomarkers of drug response, and mechanisms underlying drug resistance. We developed a number of algorithms for experimental biologists to overcome computational challenges and adopt the CRISPR technology. They include how to design a good gRNA library (18), how to quality control and analyze the CRISPR screen data (17; Li et al *Genome Biol* 2015), and how to prioritize the CRISPR screen hits for functional validation (Jiang et al, *Genome Biol* 2015). The MAGeCK suite of algorithms has been **downloaded by over 85K** and become the standard method for CRISPR screen analyses. We have also been conducting CRISPR screens to identify functional lncRNAs in cancer (19) and gene modulating T-cell mediated tumor killing (20).

17. Li W, Xu H, Xiao T, Cong L, Love MI, Zhang F, Irizarry RA, Liu JS, Brown M, Liu XS (2014). MAGeCK enables robust identification of essential genes from genome-scale CRISPR/Cas9 knockout screens. *Genome Biol* 15(12):554. PMCID:PMC4290824.
18. Xu H, Xiao T, Chen CH., Li W, Meyer CA, Wu Q, Wu D, Cong L, Zhang F, Liu JS, Brown M, Liu XS (2015). Sequence determinants of improved CRISPR sgRNA design. *Genome Res* 25(8):1147-57. PMCID: PMC4509999.
19. Zhu S, Li W, Liu J, Chen C, Liao Q, Xu P, Han Xu H, Xiao T, Cao Z, Peng J, Yuan P, Brown M, Liu XS*, Wei W* (2016). CRISPR/Cas9-mediated genomic deletion screening for long non-coding RNAs using paired-gRNAs. *Nature Biotech*. 34(12):1279-1286. PMCID: PMC5592164.
20. Pan D, Kobayashi A, Jiang P, Ferrari de Andrade L, Tay RE, Luoma A, Tsoucas D, Qiu X, Lim K, Rao P, Long HW, Yuan GC, Doench J, Brown M, Liu XS*, Wucherpennig K* (2018). A major chromatin regulator determines resistance of tumor cells to T cell-mediated killing. *Science* 359(6377):770-775. PMCID: PMC5953516.

V. Cancer immunology and therapeutics. We developed a number of algorithms integrating large-scale public genomic data to make novel discoveries related to cancer therapies, especially related to targeted and immunotherapies (22, 24). These translational cancer genomics projects include predicting anti-cancer drug response from large-scale cancer cell line drug screens (Zhang et al, *PLoS Comp Bio* 2015), deconvolve tumor-infiltrating immune cells (Li et al, *Genome Bio* 2016; Li et al *Cancer Res* 2017), infer tumor T-cell repertoires (21) and B cell repertoires (23) from TCGA tumor bulk RNA-seq data. We also collaborate with immunologists to study the role of AID in B-cell receptor diversity and genomic instability (Meng et al, *Cell* 2014).

21. Li B, Li T, Pignon JC, Wang B, Wang J, Shukla SA, Dou R, Chen Q, Hodi FS, Choueiri TK, Wu C, Hacohen N, Signoretti S, Liu JS*, Liu XS* (2016). Landscape of tumor-infiltrating T cell repertoire of human cancers. *Nat Genet*. 48(7):725-32. PMCID:PMC5298896.
22. Jiang P, Gu S, Pan D, Fu J, Sahu A, Hu X, Li Z, Traugh N, Bu X, Li B, Liu J, Freeman GJ, Brown MA, Wucherpennig KW*, Liu XS* (2018). Signatures of T cell dysfunction and exclusion predict cancer immunotherapy response. *Nat Med*. 24(10):1550-1558. PMCID: PMC6487502
23. Hu X, Zhang J, Wang J, Fu J, Li T, Zheng X, Wang B, Gu S, Jiang P, Fan J, Ying X, Zhang J, Carroll MC, Wucherpennig KW, Hacohen N, Zhang F, Zhang P, Liu JS*, Li B*, Liu XS* (2019). Landscape of B cell immunity and related immune evasion in human cancers. *Nat Genet*. 51(3):560-567. PMCID: PMC6773274
24. Cader FZ, Hu F, Goh W, Wienand K, Ouyang J, Mandato E, Redd R, Lawton L, Chen PH, Weirather J, Schackman RC, Li B, Ma W, Armand P, Rodig SJ, Neuberg D, Liu XS*, Shipp M*. A peripheral immune signature of responsiveness to PD-1 blockade in patients with classical Hodgkin lymphoma. *Nat Med*. 2020 Epub ahead of print.

D. Research Support

Ongoing Research Support

- NIH/NCI R01 CA234018 (PI: Liu XS / Wucherpfennig KW) 05/15/19 – 04/30/23
Regulators of Cancer Immunotherapy Response
We propose to integrate computational modeling and functional genomics to refine immunotherapy response biomarkers, identify novel regulators of immunotherapy response, and elucidate their underlying mechanisms.
Role: Contact PI
- NIH/NCI U01 CA226196 (PI: Liu XS) 04/06/18 – 03/31/21
Bioinformatics technology to characterize tumor infiltrating immune repertoires
We propose to develop the computational algorithms and resources to investigate T cell and B cell related immunity in tumors by utilizing tumor RNA-seq data.
Role: PI
- NIH/NCI, U24 CA237617 (Liu XS / Meyer CA) 03/15/19 – 02/29/23
Developing Informatics Technologies to Model Cancer Gene Regulation
We propose to develop bioinformatics tools to integrate and visualize ChIP-seq and chromatin accessibility profiles with transcriptome data to investigate cancer gene regulation.
Role: Contact PI
- NIH/NCI, U24 CA224316 (PI: Liu XS / Cerami E) 09/30/17 – 06/30/22
Cancer Immunologic Data Commons (CIDC)
We propose to build the infrastructure for a centralized biomarker data repository and state-of-the-art informatics tools for NCI-sponsored immunoncology clinical trials.
Role: Contact PI
- Foundation for the NIH, Inc. (PI: Liu XS / Cerami E) 09/30/17-06/30/22
Partnership for Accelerating Cancer Therapies (PACT)
This is a supplement for U24CA224316 from Foundation of the NIH where pharmaceutical companies collaborate with the CIMAC-CIDC network to profile and analyze their immunotherapy trial data.
Role: Contact PI
- Department of Defense (CDMRP) W81XWH1910551 (PI: Choueiri T / Liu XS) 09/15/19-09/14/21
Host Immune Signatures as Therapy Response Biomarkers in Metastatic Renal Cell Carcinoma
We propose to evaluate whether clonal expansion of tumor-infiltrating T cell receptors and B cell receptors in the blood can be a biomarker for kidney cancer response to immunotherapy.
Role: Co-PI.
- Breast Cancer Research Foundation BCRF-19-100 (PI: Liu XS) 10/1/17 – 9/30/20
Improve the treatment of triple negative breast cancer
We propose to integrative genomic technologies and computational modeling to improve the understanding and treatment of triple negative breast cancers.
Role: PI
- NIH/NHGRI U24 HG009446 (PI: Weng Z) 09/01/12 – 01/31/21
EDAC: ENCODE Data Analysis Center
We propose to support and enhance the integrative analyses of data from the ENCODE project.
Role: Co-Investigator
- NSFC 81872290, China (PI: Liu XS) 01/01/19 – 12/31/22
Molecular characterization of minimally invasive adenocarcinoma (MIA) of the lung
We propose to use RNA-seq of MIA and adjacent normal lung tissues to study the tumor immune microenvironment of early lung cancers.
Role: PI
- 2017YFC0908500, China (PI: Sun S.) 07/2017 – 12/2021
National key research and development plan: Building a translational clinical system to evaluate personalized medicines for malignant head and neck cancers.
Role: Collaborator



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

Nominations for Product Development Peer Review Panels

The following individuals have been recommended by Jack Geltosky, PhD (Chair, Product Development Review Council) to serve as peer reviewers for the Product Development Research Program:

Nominee	Title	Organization/Institution
Rachel Humphrey, MD	Chief Medical Officer	Black Diamond Therapeutics
Arnab Ghosh, MD, PhD	Medical Oncologist	Memorial Sloan Kettering Cancer Center
Michael Cheng, MD	Attending Physician	Dana-Farber Cancer Institute
Mickey C-T. Hu, MS, PhD	Director in discovery oncology/Principal Investigator	Panorama Institute of Molecular Medicine
Neil Vasan, MD, PhD	Assistant Attending Physician	Breast Medicine Service at Memorial Sloan Kettering Cancer Center
Walter Stadler, MD, FACP	Dean for Clinical Research	University of Chicago



Rachel Humphrey, MD

Rachel Humphrey is a medical oncologist with more than 22 years as a pharmaceutical executive. Among her many roles, she has served as both Board Director and as Chief Medical Officer for CytomX, a biotech company based in South San Francisco where she supervised the clinical development of Probody™ Therapeutics for the development of cancer. Prior to this, she held various senior level roles in cancer drug development including AstraZeneca (SVP, Head of the Immuno-oncology department), and Bristol Myers Squibb (VP, Clinical Development). Dr. Humphrey's career is notable for, among other things, overall supervision of the (early and late-stage) clinical development of ipilimumab (Yervoy) at BMS and sorafenib (Nexavar) at Bayer. She is also the lead singer and one of the co-founders of the band, The Checkpoints, a blues band made up of luminaries in immuno-oncology, including the Nobel Laureate, Jim Allison, and is featured in the movie "Jim Allison: Breakthrough", which was released in the fall of 2019.

Curriculum Vitae**Rachel Wallach Humphrey, MD**

Current address Princeton, NJ 08540,

Educated Harvard College, Cambridge, MA, 1979-1984
CWRU Medical School, Cleveland, Ohio 1985-1989

Postgraduate Johns Hopkins Hospital (Internal Medicine) 1989-1992
National Cancer Institutes (Medical Oncology) 1992-1997

Summary of Experience

- Senior pharmaceutical executive with extensive experience in product development at the level of biotech Board Director of a small private company, biotech Chief Medical Officer and large pharma Therapeutic Area Head.
- Extensive experience interacting externally with investors, analysts, scientific leaders and large and small pharma collaborators. This includes key participation in the CytomX IPO and follow-on financing as Chief Medical Officer.
- In the role of Director in the CytomX Board: supervision of company activities during a robust period of growth, Mezzanine financing and pre-IPO activities. The transition to the role of CMO within that first year, and at the time the S1 was filed, was designed to support the IPO roadshow and provide full-time attention in order to help ensure the success of the pipeline.
- Proven success in managing Product Development strategy and tactics for over 22 years: small molecules, cytotoxics and biologics from pre-IND to compound commercialization in immuno-oncology and oncology, including senior-most oversight and successful development of 2 new molecular entities in oncology: YERVOY (*ipilimumab*) and NEXAVAR (*sorafenib*).

- In the role of Chief Medical Officer at CytomX, supervised the evolution of the company from “research only” to “clinical stage” with the creation of a high performing, full-service clinical development organization with over 40 employees, and concurrent evolution of the organizational processes, structure and culture required for success.
- As Senior Vice President and Head of Immuno-Oncology at AstraZeneca, created the late-stage Immuno-Oncology department and supervised the clinical development of INFINZI (*durvalumab*), directing the design and initiation of multiple registrational studies in the first year, including the successful PACIFIC study, which led to global approval and helped AstraZeneca achieve commercial success in NSCLC.
- Featured in the film Breakthrough, a documentary which details the life and work of Jim Alison and his key partners in the development of YERVOY. The film opened country-wide in select theaters in September, 2019.

Positions held

- 2019 – Present Pharmaceutical Consultant
 - 2020 Head of R&D, TIO Bioventures Discovery Engine
- 2015 - 2019 Chief Medical Officer, CytomX
 - 2015 Board of Directors, CytomX
 - 2015 Vice President, Head of IO, Lilly and Company
- 2013 - 2014 Senior Vice President, Head of IO, Astrazeneca
- 2012 – 2013 Executive Vice President, Chief Medical Officer, Mirati Therapeutics (formerly MethylGene Inc).

- 2005 – 2012 Vice President, Product Development, BMS
- 2003 – 2005 Executive Director, Product Development, BMS
- 2002 - 2003 Director, Global Clinical Development, Bayer Pharmaceuticals
- 1998 - 2002 Deputy Director, Global Clinical Development, Bayer Pharmaceuticals
- 1997 - 1998 Associate Director, Global Clinical Development, Bayer Pharmaceuticals
- 1995 - 1997 Staff Physician-Scientist, National Cancer Institute, HIV and AIDS Malignancy Branch
- 1992 - 1995 Clinical Oncology Fellow, National Cancer Institute
- 1989 - 1992 Internal Medicine Resident, The Johns Hopkins Hospital

Pharmaceutical Industry Experience Details

CytomX Therapeutics (San Francisco, California) *Chief Medical Officer (Aug 2015 – Aug 2019)*

- Member of the CEO's Executive Team
- Member of the IPO roadshow team (Sept 2015)
- Built the global clinical development organization with all relevant development functions, including marketing
- Oversaw of all aspects of global clinical development of the CytomX portfolio, including the clinical and pre-clinical compounds
- Supervised the IND submissions, designs, initiations and conduct of all phase I, Ib and II studies for the first 3 Probody therapeutics to enter the clinic, as well as the overall global development strategy: CX-072 (PD-L1 probody), CX-2009 (CD166 probody drug conjugate), CX-2029 (CD71 probody drug conjugate), CX-188 (PD-1 probody), and other pipeline programs

CytomX Board of Directors (Mar 2015 – Aug 2015)**AstraZeneca Pharmaceuticals (Gaithersburg, MD):*****Senior Vice President, Head Immuno-Oncology (Nov 2013 - Nov 2014)***

- Member of the CMO's Senior Executive Team and Oncology Operating Committee
- Accountable for overall late-stage strategy for all Immuno-Oncology agents in development: IMFINZI (*durvalumab*), *tremelimumab* and the combination of IMFINZI and *tremelimumab*
- Created a full-sized late-stage development team and initiated a large full-scale development program for both major assets and the combination all within the first year.
- Supervised and/or directly participated in routine interactions with global Regulatory Authorities, Investors and Analysts

Mirati Therapeutics (formerly MethylGene Inc; Montreal Canada)***Executive Vice President, Chief Medical Officer (Jan 2012 – Sept 2013)***

- Supervised all drug development functions, rebuilding the team after a meaningful contraction.
- Oncology and Infectious disease portfolio; *glesatinib* (MEK and AXL inhibitor; anti-cancer; phase I/II), *sitravatinib* (Tyrosine kinase inhibitor; anti-cancer; preclinical), *mocetinostat* (HDAC inhibitor, anti-cancer; phase II) and MGCD290 (hos inhibitor, anti-fungal; phase II)

Bristol-Myers Squibb (Lawrenceville, NJ)***VP, Clinical Development and Head of Ipilimumab Program (May 2005 – Jan 2012)***

- Supervised all aspects of the clinical development of the CTLA-4 antagonist monoclonal antibody (YERVOY, *ipilimumab*) in melanoma, with over 100 dotted-line reports, BLA submissions, interfacing with global regulatory authorities and simultaneous NEJM publications with plenary presentations at ASCO (2010 and 2011)
- Supervised the Medarex Alliance in the strategic and tactical management of Phase I – III
- Developed the “immune-related response criteria” for the measurement of efficacy in patients receiving immunotherapies such as YERVOY (*ipilimumab*).
- Supervised the in-licensing of *vinflunine* and personally supervised all aspects of clinical development through the initiation and/or conduct of phase II and III.
- Supervised the in-licensing of CABOMETYX (*cabozantinib*) and clinical development in the Alliance between BMS and Exelixis, including introduction of the highly successful randomized discontinuation design into the clinical development program.

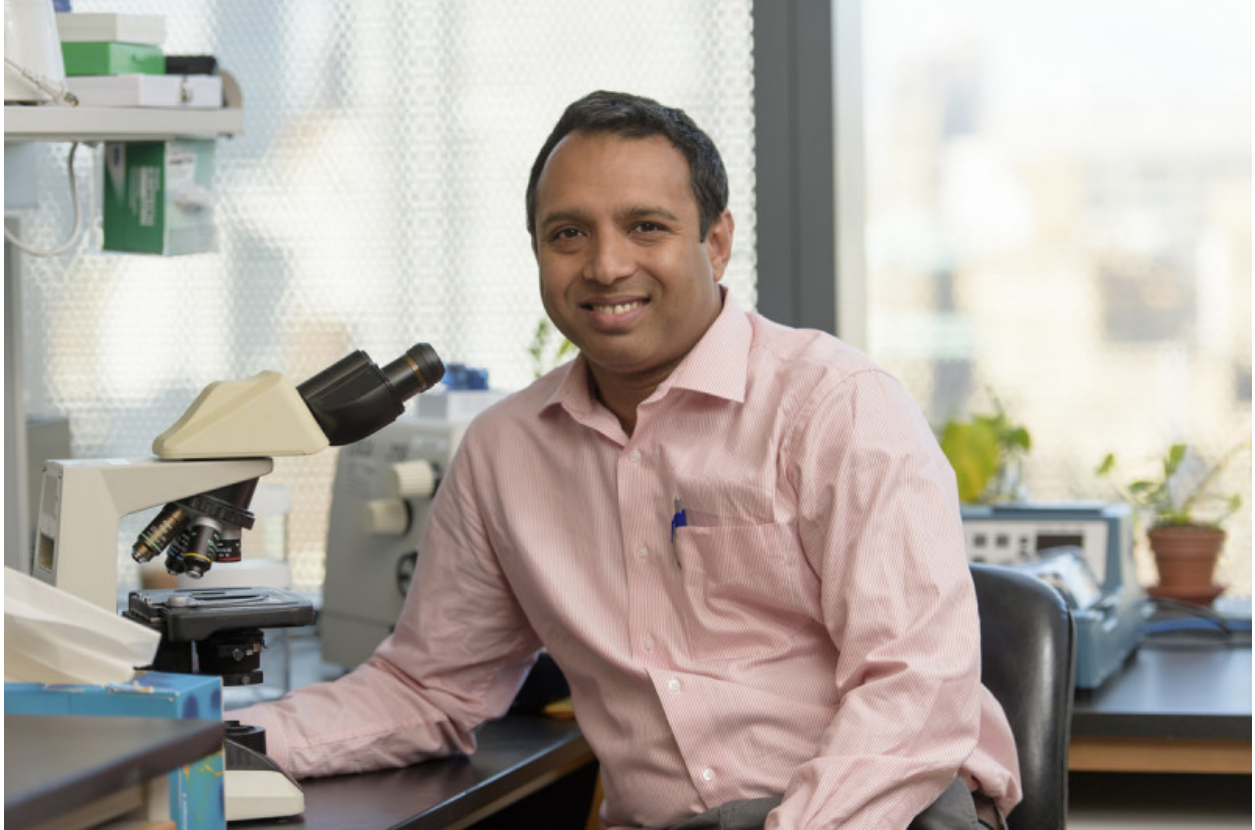
Bayer Pharmaceuticals (West Haven, Connecticut)***Associated Director (1997 – 1998) Deputy Director (1998 – 1999) Director (1999 – May 2003)***

- Supervised the global and US Phase I, II and III Clinical Research in oncology for multiple clinical assets
- Supervised all aspects of phase I - III clinical development for NEXAVAR (*sorafenib*) in renal cell cancer (in collaboration with Onyx Pharmaceuticals) and phase I in melanoma for the IL-2 selective agonist (to “no go”) including IND submissions, post-phase 2 Regulatory interactions, design/ conduct of pivotal program

- Introduced the “randomized discontinuation study” design into clinical development of NEXAVAR (*sorafenib*)

Publications: over 40 peer-reviewed articles or abstracts (available on request), including a seminal paper on Ipilimumab in the New England Journal of Medicine, and senior authorship on the first introduction of the new Immune-Related Response Criteria in Clinical Cancer Research, and a summary of ongoing research activities during the COVID-19 pandemic in The Cancer Letter.

Outside of work: Founder of the Checkpoints Blues Bands and lead singer since 2007, performing at the Chicago House of Blues and/or Buddy Guys during ASCO week. We also perform at a variety of venues during other annual congresses, and periodically by invitation to non-congress events in the US and Europe. The band is composed of Immuno-oncology experts (scientists and doctors), all of whom collaborated in some form in the development of ipilimumab, including the Nobel prize recipient, Jim Alison (on blues harmonica).



Arnab Ghosh, MD, PhD

I am a medical oncologist in the adult Bone Marrow Transplantation Service at Memorial Sloan Kettering Cancer Center. I attended medical school in Mysore, India and obtained a PhD in Molecular Medicine from Medical School in Hannover, Germany. I study how responses to immunotherapies in cancer are affected by interactions between the immune cells, the tumors and their microenvironment. In the past, my research has focused on adoptively transferred cell therapies including chimeric antigen receptor T cells. More recently, I have focused on using small molecule therapies to reprogram the tumor microenvironment to augment the effects of immune checkpoint blockade and T cell based immunotherapies.

Date Of Preparation: 7/2020

Arnab Ghosh MD, PhD

Assistant Attending Physician
Adult BMT service/ Department of Medicine
Memorial Sloan Kettering Cancer Center, NY
1275 York Av,
New York, New York 10065
E-Mail: GhoshA@MSKCC.org

Education

M.B.B.S. (U.S. M.D. equivalent) **05/2003**
Mysore Medical College,
Rajiv Gandhi University of Health Sciences, India

Ph.D. **06/2007**
Immunology
Medizinische Hochschule Hannover, Germany

Residency **07/2013- 06/2015**
Internal Medicine Program-Research Track
Icahn School of Medicine at Mount Sinai, NY

Clinical Fellow **07/2015- 06/2019**
Hematology/Medical Oncology
Memorial Sloan Kettering Cancer Center, NY

Professional Experience

Assistant Attending Physician **07/2019- Current**
Adult BMT/ Div of Hematologic Malignancies
Department of Medicine
Memorial Sloan Kettering Cancer Center, NY

Postdoctoral Associate **05/2008- 06/2013**
Immunology, Memorial Sloan-Kettering Cancer Center, NY
Supervisor: Dr. Marcel R.M. van den Brink, M.D.,Ph.D, Head, Div. of Hematologic Oncology.

Doctoral Student **10/2003- 05/2008**
Bone Marrow Transplantation, Medizinische Hochschule Hannover, Germany
Supervisor: Dr. Martin Sauer, M.D.,Ph.D., Dept. of Pediatric Oncology.
Thesis: Adoptive transfer of immunologically engineered T cells as immunotherapeutic agents for hematological malignancies

Senior Research Fellow **08/2002-09/2003**
Immunology, Advanced Center for Training, Research and Education of Cancer
Tata Memorial Center, Mumbai, India
Supervisor: Dr. Shubhada Chiplunkar, Ph.D., Immunology

Grants/ Fellowship

Merck Immunotherapy Clinical Fellowship , Society for Immunotherapy of Cancer	2017
Fellowship , Lymphoma Research Foundation	2011
Dr. Judah Folkman Award , American Association of Cancer Research	2010
Dr. Mildred-Scheel Fellowship , German Cancer Aid, Germany	2008
Senior Research Fellowship , Council for Scientific and Industrial Research, India	2003

Awards

SITC MeTIOR , Society for Immunotherapy of Cancer	2018
Young Investigator Symposium , ECOG-ACRIN	2015
Trainee Abstract Award , American Association of Immunologists	2013
Abstract Achievement Award , American Society of Hematology (ASH)	2012
Abstract Achievement Award , American Society of Hematology (ASH)	2011
Travel Award , American Society of Hematology (ASH)	2010
Best Outgoing Graduate , Mysore Medical College, India	2002

Academic Profile

Publications

Original Research

Maluski M, **Ghosh A**, Herbst J, Scholl V, Baumann R, Huehn J, Geffers R, Meyer J, Maul H, Eiz-Vesper B, Krueger A, Schambach A, van den Brink MR, Sauer MG. Chimeric antigen receptor-induced BCL11B suppression propagates NK-like cell development. *J Clin Invest*. 2019 Dec 2;129(12):5108-5122

Ghosh A, Smith M, James S, Davila ML, et al. Donor CD19 CAR T cells exert potent graft-versus lymphoma activity with diminished graft-versus-host activity. *Nat Med*. 2017 Feb;23(2):242-249

De Henau O, Rausch M, Winkler D, Campesato LF, Liu C, Cyster DH, Budhu S, **Ghosh A**, Pink M, Tchaicha J, et al. Overcoming resistance to checkpoint blockade therapy by targeting PI3K γ in myeloid cells. *Nature*. 2016 Nov 17;539(7629):443-447

Hübner J, Hoseini SS, Suerth JD, Hoffmann D, Maluski M, Herbst J, Maul H, **Ghosh A** et al. Generation of Genetically Engineered Precursor T-Cells From Human Umbilical Cord Blood Using an optimized alpharetroviral vector platform. *Mol Ther*. 2016 Aug;24(7):1216-26

Ghosh A, Dogan Y, Moroz M, Holland AM et al. Adoptively transferred TRAIL⁺ T cells suppress GVHD and augment antitumor activity. *J Clin Invest*. 2013 Jun 3;123(6):2654-62

Ghosh A, Holland AM, Dogan Y, Yim N et al. PLZF Confers Effector Functions to Donor T Cells That Preserve Graft-versus-Tumor Effects while Attenuating GVHD. *Cancer Res*. 2013 Aug 1;73(15):4687-4696.

Tsai JJ, Dudakov JA, Takahashi K, Shieh JH, Velardi E, Holland AM, Singer NV, West ML, Smith OM, Young LF, Shono Y, **Ghosh A** et al Nrf2 regulates haematopoietic stem cell function. *Nat Cell Biol*. 2013 Mar;15(3):309-16

Hanash AM, Dudakov JA, Hua G, O'Connor MH, Young LF, Singer NV, West ML, Jenq RR, Holland AM, Kappel LW, **Ghosh A** et al. Interleukin-22 protects intestinal stem cells from immune-mediated tissue damage and regulates sensitivity to graft versus host disease. *Immunity*. 2012 Aug 24;37(2):339-50

Dudakov JA, Hanash AM, Jenq RR, Young LF, **Ghosh A** et al. Interleukin-22 Drives Endogenous Thymic Regeneration in Mice. *Science*. 2012 Apr 6;336(6077):91-5

Jenq RR, Ubeda C, Taur Y, Khanin RM, Dudakov JA, Liu C, West ML, Singer NV, Equinda MJ, Gobourne A, Lipuma L, Young LF, Smith OM, **Ghosh A**, Holland AM et al. Regulation of intestinal inflammation by microbiota following allogeneic bone marrow transplantation. *J Exp Med*. 2012 May 7;209(5):903-11

del Rio ML, Kurtz J, Perez-Martinez C, **Ghosh A**, Rodriguez-Barbosa J. BTLA Targeting Protects against the Acute Phase of GvHR by Inhibiting Donor anti-Host Cytotoxicity *Transplantation*. 2011 Nov 27;92(10):1085-93

Penack O, Henke E, Suh D, King CG, Smith OM, Na IK, Holland AM, **Ghosh A**, et al. Inhibition of neovascularization to simultaneously ameliorate graft-vs-host disease and decrease tumor growth. *J Natl Cancer Inst*. 2010 Jun 16;102(12):894-908

Na IK, Markley JC, Tsai JJ, Yim NL, Beattie BJ, Klose AD, Holland AM, **Ghosh A**, et al. Concurrent visualization of trafficking, expansion and activation of T lymphocytes and T-cell precursors in vivo. *Blood*. 2010 Sep 16;116(11):e18-25

Na IK, Lu SX, Yim NL, Goldberg GL, Tsai J, Rao U, Smith OM, King CG, Suh D, Hirschhorn-Cymerman D, Palomba L, Penack O, Holland AM, Jenq RR, **Ghosh A**, et al. The cytolytic molecules Fas ligand and TRAIL are required for murine thymic graft-versus-host disease. *J Clin Invest*. 2010 Jan;120(1):343-56

Penack O, Smith OM, Cunningham-Bussel A, Liu X, Rao U, Yim N, Na IK, Holland AM, **Ghosh A**, et al. NOD2 regulates hematopoietic cell function during graft-versus-host disease. *J Exp Med*. 2009 Sep 28;206(10):2101-10

Ghosh A, Koestner W, Hapke M, Schlaphoff V, Langer F, Baumann R, Koenecke C, Cornberg M, Welte K, Blazar B, Sauer MG: Donor T cells primed on leukemia lysate-pulsed recipient APCs mediate strong graft versus leukemia effects across MHC barriers in full chimeras. *Blood*. 2009 Apr 30;113(18):4440-8

Ghosh A, Wolenski M, Klein C, Welte K, Blazar BR, Sauer MG. Cytotoxic T cells reactive to an immunodominant leukemia-associated antigen can be specifically primed and expanded by combining a specific priming step with nonspecific large-scale expansion. *J Immunother*. 2008 Feb-Mar;31(2):121-31

Rathinam C, Sauer M, **Ghosh A**, et al. Generation and characterization of a novel hematopoietic progenitor cell line with DC differentiation potential. *Leukemia*. 2006 May;20(5):870-6

Sauer M, Bettoni C, Lauten M, **Ghosh A**, et al. Complete substitution of cyclophosphamide by fludarabine and ATG in a busulfan-based preparative regimen for children and adolescents with beta-thalassemia. *Bone Marrow Transplant*. 2005 Sep;36(5):383-7

Reviews:

Ghosh A, Barba P, Perales MA. Checkpoint inhibitors in AML: are we there yet?. *Br J Haematol*. 2020 Jan;188(1):159-167.

Ghosh A, Politikos I, Perales MA. Stop and go: hematopoietic cell transplantation in the era of chimeric antigen receptor T cells and checkpoint inhibitors. *Curr Opin Oncol*. 2017 Nov;29(6):474-483.

Ghosh A, Mailankody S, Giralto SA, Landgren CO, Smith EL, Brentjens RJ. CAR T cell therapy for multiple myeloma: where are we now and where are we headed? *Leuk Lymphoma*. 2018 Sep;59(9):2056-2067

Ghosh A, Holland AM, van den Brink MR. Genetically engineered donor T cells to optimize graft-versus-tumor effects across MHC barriers. *Immunol Rev*. 2014 Jan;257(1):226-36

Holland AM, Zakrzewski JL, Goldberg GL, **Ghosh A**, van den Brink MR: Adoptive precursor cell therapy to enhance immune reconstitution after hematopoietic stem cell transplantation in mouse and man. *Semin Immunopathol*. 2008 Dec;30(4):479-87

Book Chapters

Ghosh A, Cai S Ch 28. Benign hematology: Hematopoiesis *Pocket Oncology (Pocket Notebook) Second Edition* Ed. Drilon, Postow, Vasan, Carlo Wolters Kluwer Philadelphia. 2018. Print

Ghosh A, Mantha S Ch 28. Benign hematology: Hypercoagulable states *Pocket Oncology (Pocket Notebook) Second Edition* Ed. Drilon, Postow, Vasan, Carlo Wolters Kluwer Philadelphia. 2018. Print

Selected Presentations

Mailankody S, **Ghosh A**, M Staehr, Clinical Responses and Pharmacokinetics of MCARH171, a Human-Derived Bcma Targeted CAR T Cell Therapy in Relapsed/Refractory Multiple Myeloma: Final Results of a Phase I Clinical Trial (*ASH Annual Meeting 2018*)

Ghosh A, Flow Cytometry Based Detection of MRD in Bone Marrow of Patients with Multiple Myeloma: A Comparison Between Fluorescent-Based Cytometry Versus CyTOF (*ASH Annual Meeting 2015*)

Ghosh A, Davila M et al Donor CD19-targeted T cells exert potent graft versus lymphoma activity without GVHD (*AAI Annual Meeting 2013*)

***Oral presentation, Trainee award**

Ghosh A, Davila M et al CD19-targeted donor T cells exert potent graft-versus-lymphoma activity and attenuated GVHD (*ASH Annual Meeting 2012*)

***Oral presentation, Abstract achievement award**

Ghosh A, Dogan Y et al Genetic engineering of donor T cells for BMT immunotherapy: Over-expression of TRAIL on donor T cells enhances GVT and suppresses GVHD via elimination of alloreactive T cells and host APC. (*ASH Annual Meeting 2011*)

***Oral presentation, Abstract achievement award, Highlighted at the ASH press program**

Ghosh A, Holland AM et al Genetic engineering of donor T cells for BMT immunotherapy: Expression of TRAIL and PLZF selectively enhances GVT and abrogates GVHD (*AACR Annual Meeting 2011*)

***Oral presentation.**

Ghosh A, Holland AM et al Genetic engineering of donor T cells for BMT immunotherapy: Expression of TRAIL and PLZF selectively enhances GVT and abrogates GVHD (*ASH Annual Meeting 2010*)

***Oral presentation and Travel award**

Ghosh A., Hapke et al. Allogeneicity of antigen-presenting cells plays a crucial role for graft-versus-leukaemia effects after adoptive transfer of leukaemia-reactive cytotoxic T-cells *Bone Marrow Transplantation (EBMT 2007)*

***Oral presentation at the Presidential symposium.**

Other Activities

- Associate Editor: BMC Cancer 2017

- Project leader: Team Checkpoints, SITC MeTIOR program

- Manuscript Review: Blood, Molecular Therapy, New England Journal of Medicine

Certifications

Educational Commission for Foreign Medical Graduates (ECFMG) certification 06/07/2012

American Board of Internal Medicine: Internal Medicine Board certification 2016

American Board of Internal Medicine: Medical Oncology Board certification 2018

Languages Spoken

Native fluency: English, Bengali, Hindi

Working proficiency: German, Kannada

Hobbies

Traveling, Photography.



Biography

Michael L. Cheng, MD is an attending physician at the Dana-Farber Cancer Institute and an Instructor in Medicine at Harvard Medical School. Dr. Cheng received his M.D. from the UCLA David Geffen School of Medicine, where he graduated with Alpha Omega Alpha honors. He completed his residency in Internal Medicine at the University of California, San Francisco and his fellowship in Medical Oncology at Memorial Sloan Kettering Cancer Center. Dr. Cheng leads clinical and translational research centered on precision oncology for non-small cell lung cancer (NSCLC), with a focus on leveraging plasma and tumor next-generation sequencing (NGS) data to elucidate tumor biology and inform the development of next-generation targeted therapies and immunotherapies. Dr. Cheng strives to provide individualized, compassionate care and continues to be inspired by the tangible and substantial patient benefit driven by research advances.

**Harvard Medical School
Curriculum Vitae**

Date Prepared: 07/24/20
Name: Michael L. Cheng
Office Address: 450 Brookline Ave, Dana 1240K, Boston, MA 02215
Home Address:
Work Phone: 617-632-3468
Work Email: michael_cheng@dfci.harvard.edu
Work FAX: 617-632-5786
Place of Birth: California, USA

Education

2008	BA	Molecular Cell Biology	University of California, Berkeley, CA
2012	MD	Medicine	University of California, Los Angeles, CA

Postdoctoral Training

06/12-06/15	Resident	Internal Medicine (Categorical)	University of California, San Francisco, CA
07/15-06/18	Fellow	Medical Oncology	Memorial Sloan Kettering Cancer Center, New York, NY

Faculty Academic Appointments

07/18-present	Instructor	Medicine	Harvard Medical School, Boston, MA
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Appointments at Hospitals/Affiliated Institutions

06/12-06/15	Resident	Internal Medicine	University of California, San Francisco
07/15-06/18	Fellow	Medical Oncology	Memorial Sloan Kettering Cancer Center
07/18-present	Physician	Medical Oncology	Brigham and Women's Hospital
07/18-present	Physician	Medical Oncology	Dana-Farber Cancer Institute

Committee Service

Local

2009-2010	Admissions Committee 2009-2010	University of California, Los Angeles David Geffen School of Medicine
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Professional Societies

2016-present	American Society of Clinical Oncology (ASCO)
2016-present	American Association for Cancer Research (AACR)
2017-present	International Association for the Study of Lung Cancer (IASLC)

Grant Review Activities

2018-present	Young Investigator and Challenge Award Peer Reviewer	Prostate Cancer Foundation
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Editorial Activities

Ad hoc Reviewer

Lung Cancer (Elsevier)
JCO Precision Oncology
British Journal of Cancer
Clinical Cancer Research

Honors and Prizes

2004	Regents' and Chancellor's Scholar	University of California, Berkeley	
2007	Alumni Association Leadership Scholar	University of California, Berkeley	
2008	High Distinction in General Scholarship	University of California, Berkeley	
2008	Phi Beta Kappa	University of California, Berkeley	
2009	Department of Medicine Chiefs' Research Fellowship	University of California, Los Angeles	
2011	Letters of Distinction (six)	University of California, Los Angeles	Awarded for "exemplary performance" during core clerkships
2011	Global Health Program Scholarship	University of California, Los Angeles	
2012	Alpha Omega Alpha	University of California, Los Angeles	
2014	Clinical and Translational Science Institute (CTSI) Resident Research Travel Grant	University of California, Los Angeles	
2017	ASCO Conquer Cancer Foundation Merit Award (2017 Annual Meeting)	American Society of Clinical Oncology	

2017 NIH Clinical Loan Repayment Program Award (National Cancer Institute) National Institutes of Health

Report of Funded Projects

Current

- 2017-2020 Mediators of intrinsic sensitivity and acquired resistance to PARP inhibition for the treatment of BRCA-mutant castrate resistant prostate cancer
Prostate Cancer Foundation Young Investigator Award
PI (\$225,000 - total direct costs)
This project seeks to correlate BRCA genotypes and genomic measures of HRD with response rate to PARP inhibitors and platinum chemotherapies, and to identify molecular mechanisms of acquired resistance to these therapies.
- 2019-2023 Pilot study of serial plasma genotyping to guide the adaptive treatment of advanced NSCLC receiving first-line pembrolizumab
ASCO Career Development Award (2020-2023)
PI (\$200,000 – total costs)
Dunkin Translational Breakthrough Grant
PI (\$150,000 – total costs)
DF/HCC Lung Cancer Program Developmental Research Project Award
PI (\$60,000 – total costs)
DFCI Cancer Care Collaborative Research Award
PI (\$103,000 – direct costs)
This project seeks to conduct a prospective pilot trial where early plasma response guides adaptive treatment of first-line advanced NSCLC receiving pembrolizumab and study the application of plasma response to clinical care in NSCLC.
- 2020-2021 Characterization of Siglec ligands in advanced NSCLC treated with PD-(L)1 checkpoint blockade
Palleon Pharmaceuticals Collaboration Research Agreement
PI (\$84,164 – total costs)
This project seeks to characterize the expression of Siglec ligands in NSCLC tumor tissue, evaluate serum glycoproteomic signatures, and correlate these findings to clinical outcomes.

Report of Local Teaching and Training

Formal Teaching of Residents, Clinical Fellows and Research Fellows (post-docs):

- | | | |
|-----------|--|--|
| 2018-2019 | Fellows' Conference – NSCLC Staging
1 st year and other Medical Oncology fellows | Dana-Farber Cancer Institute,
Boston, MA
One-hr lectures |
| 2019 | Fellows' Conference – NTRK Fusions
1 st year and other Medical Oncology fellows | Dana-Farber Cancer Institute,
Boston, MA
One-hr lecture |

Clinical Supervisory and Training Responsibilities:

2018-present	Attending Physician (Inpatient Oncology) Resident Physicians and Physician Assistants	DFCI/BWH Boston, MA
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Formal Teaching of Peers (e.g., CME and other continuing education courses):

2019	Advancements in First-Line Therapeutics for NSCLC Navigation of Current Treatment Options for Stage IV Non-Squamous NSCLC Potomac Center for Medical Education (supported by Lilly and Merck)	3 Rahway, NJ; Philadelphia, PA; Rockville, MD
2019	Improving Outcomes for Patients with NSCLC in China: New Approaches and Clinical Updates WebMD (supported by AstraZeneca)	1 Shanghai, China

Report of Regional, National and International Invited Teaching and Presentations:

International

2019	IASLC Targeted Therapies Meeting – CSF-1R	Santa Monica, CA
2020	IASLC Targeted Therapies Meeting – ASN 007	Santa Monica, CA

Report of Clinical Activities and Innovations

Current Licensure and Certification

2015	Certification, American Board of Internal Medicine (Internal Medicine)
2017	Certification, American Board of Internal Medicine (Medical Oncology)
2018	Massachusetts Medical License

Practice Activities

2018-present	Ambulatory Care	Medical Oncology, Dana-Farber Cancer Institute	Four half-day sessions per week
2018-present	Inpatient Care	Medical Oncology, Dana-Farber Cancer Institute and Brigham and Women's Hospital	Approximately two weeks per year

Report of Scholarship

Research investigations

1. **Cheng ML**, Zhang L, Borok M, Chokunonga E, Dzamamala C, Korir A, Wabinga HR, Hiatt RA, Parkin DM, Van Loon K. The incidence of oesophageal cancer in Eastern Africa: Identification of a new geographic hot spot? Cancer Epidemiol 2015; 39: 143-9. PubMed PMID: 25662402; PubMed Central PMCID: PMC4470609
2. Razavi P, Chang MT, Xu G, Bandlamudi C, Ross DS, Vasan N, Cai Y, Bielski CM, Donoghue MTA, Jonsson P, Penson A, Shen R, Pareja F, Kundra R, Middha S, **Cheng ML**, Zehir A, Kandath C, Patel R, Huberman K, Smyth LM, Jhaveri K, Modi S, Traina TA, Dang C, Zhang W, Weigelt B, Li BT, Ladanyi M, Hyman DM, Schultz N, Robson ME, Hudis C, Brogi E, Viale A, Norton L, Dickler MN, Berger MF, Iacobuzio-Donahue CA, Chandarlapaty S, Scaltriti M, Reis-Filho JS, Solit DB,

- Taylor BS, Baselga J. The Genomic Landscape of Endocrine-Resistant Advanced Breast Cancers. *Cancer Cell* 2018 Sep 10;34(3):427-438.e6. PubMed PMID: 30205045
3. Abida W, **Cheng ML**, Armenia J, Middha S, Autio KA, Vargas HA, Rathkopf DE, Morris MJ, Danila DC, Slovin SF, Carbone E, Hullings M, Hechtman JF, Zehir A, Shia J, Jonsson P, Stadler ZK, Srinivasan P, Laudone VP, Reuter VE, Wolchok JD, Socci ND, Taylor BS, Berger MF, Kantoff PW, Sawyers CL, Schultz N, Solit DB, Gopalan A, Scher HI. Analysis of the Prevalence of Microsatellite Instability in Prostate Cancer and Response to Immune Checkpoint Blockade. *JAMA Oncol* 2019 Apr 1;5(4):471-478. PubMed PMID: 30589920
 4. Jonsson P, Bandlamudi C, **Cheng ML**, Srinivasan P, Chavan SS, Friedman ND, Rosen EY, Richards AL, Bouvier N, Selcuklu SD, Bielski CM, Abida W, Mandelker D, Birsoy O, Zhang L, Zehir A, Donoghue MTA, Baselga J, Offit K, Scher HI, O'Reilly EM, Stadler ZK, Schultz N, Socci ND, Viale A, Ladanyi M, Robson ME, Hyman DM, Berger MF, Solit DB, Taylor BS. Tumour lineage shapes BRCA-mediated phenotypes. *Nature* 2019 Jul;571(7766):576-579. PubMed PMID: 31292550.
 5. Postow MA, Chasalow SD, Kuk D, Panageas KS, **Cheng ML**, Yuan J, Wolchok JD. Absolute lymphocyte count as a prognostic biomarker for overall survival in patients with advanced melanoma treated with ipilimumab. *Melanoma Res* 2019 Aug 14. PubMed PMID: 31425479
 6. Sands JM, Nguyen T, Shivdasani P, Sacher AG, **Cheng ML**, Alden RS, Jänne PA, Kuo FC, Oxnard GR, Sholl LM. Next-generation sequencing informs diagnosis and identifies unexpected therapeutic targets in lung squamous cell carcinomas. *Lung Cancer*. 2019 Dec 16. PubMed PMID: 31855703.
 7. Ricciuti B, Recondo G, Spurr LF, Li YY, Lamberti G, Venkatraman D, Umeton R, Cherniack AD, Nishino M, Sholl LM, Shapiro GI, Awad MM*, **Cheng ML***. Impact of DNA damage response and repair (DDR) gene mutations on efficacy of PD-(L)1 immune checkpoint inhibition in non-small cell lung cancer. *Clin Cancer Res* 2020 Apr 24. pii: clincanres.3529.2019. doi: 10.1158/1078-0432.CCR-19-3529. [Epub ahead of print]

Other peer-reviewed publications

1. **Cheng ML**, Leibowitz M, Ha E. Coccidioidal endophthalmitis in immunocompetent person, California, USA. *Emerg Infect Dis* 2012; 18: 1015–6. Pubmed PMID: 22608196; PubMed Central PMCID: PMC3358163.
2. Ryan CJ, **Cheng ML**. Abiraterone acetate for the treatment of prostate cancer. *Expert Opin Pharmacother* 2013; 14: 91–6. PubMed PMID: 23199349
3. **Cheng ML**, Fong L. Effects of RANKL-Targeted Therapy in Immunity and Cancer. *Front Oncol* 2014; 3: 329. PubMed PMID: 24432249; PubMed Central PMCID: PMC3882875
4. **Cheng ML**, Fong L. Beyond Sipuleucel-T: Immune Approaches to Treating Prostate Cancer. *Curr Treat Options Oncol* 2014; 15: 115-26. PubMed PMID: 24402184; PubMed Central PMCID: PMC4523381
5. **Cheng ML**, Solit DB. Opportunities and challenges in genomic sequencing for precision cancer care. *Ann Intern Med* 2018; 168: 221-2. PubMed PMID: 29310131
6. **Cheng ML**, Iyer G. Novel Biomarkers in Bladder Cancer. *Urol Oncol*. 2018; 36: 115-9. PubMed PMID: 29472156
7. **Cheng ML**, Berger MF, Hyman DM, Solit DB. Clinical tumour sequencing for precision oncology: time for a universal strategy. *Nat Rev Cancer*. 2018 Sep;18(9):527-528. PubMed PMID: 30030494.
8. **Cheng ML**, Oxnard GR. Does TMB impact the effectiveness of TKIs in EGFR-mutant NSCLC? *Clin Cancer Res*. 2019 Feb 1;25(3):899-900. PubMed PMID: 30190372

Non-peer reviewed scientific or medical publications/materials in print or other media

- Books/Textbooks for the medical or scientific community

1. **Cheng ML**, Scher HI. Localized Prostate Cancer. In: Pocket Oncology, 2nd edition, Carlo MI and Vasan N, Eds. 2019.

Abstracts, Poster Presentations and Exhibits Presented at Professional Meetings

1. Audenet F, Donoghue M, Pietzak EJ, Isharwal S, **Cheng ML**, Iyer G, Funt SA, Bajorin DF, Al-Ahmadie HA, Reuter VE, Eng J, Reichel JB, Arcila ME, Tsui DW, Shady M, Berger MF, Bosl GJ, Sheinfeld J, Solit DB, Feldman DR. Genomic comparison of matched primary and metastatic germ cell tumors (GCT). *J Clin Oncol* 35, 2017 (suppl; abstr 4556). Poster Session (presented as Alternate Presenter), June 2017. ASCO Annual Meeting; Chicago, IL.
2. **Cheng ML**, Shady M, Cipolla CK, Funt SA, Arcila ME, Al-Ahmadie HA, Rosenberg JE, Bajorin DF, Berger MF, Tsui DW, Solit DB, Iyer G. Comparison of somatic mutation profiles from cell free DNA (cfDNA) versus tissue in metastatic urothelial carcinoma (mUC). *J Clin Oncol* 35, 2017 (suppl; abstr 4533). Poster Session, June 2017. ASCO Annual Meeting; Chicago, IL.
3. **Cheng ML**, Abida W, Rathkopf D, Arcila ME, Barron D, Autio KA, Zehir A, Danila DC, Morris MJ, Gopalan A, Reuter VE, Kantoff PW, Slovin SF, Robson ME, Zhang L, Mandelker D, Tsui DW, Taylor BS, Solit DB, Scher HI. Next-generation sequencing (NGS) of tissue and cell free DNA (cfDNA) to identify somatic and germline alterations in advanced prostate cancer. *J Clin Oncol* 35, 2017 (suppl; abstr 5010). Poster Discussion Session, June 2017. ASCO Annual Meeting; Chicago, IL.
4. Yang JL, Marass F, Ulz P, Shady M, **Cheng ML**, Kothari P, Somnay S, Shukla N, Modak S, Slotkin E, Kathkopf D, Gopaumar I, Scher HI, Ravazi P, Feldman D, Li B, Chapman P, Rosenberg J, Bajorin D, Berger MF, Seshan VE, Socci ND, Solit DB, Heitzer E, Tsui DWY. Shallow Whole Genome Sequencing of Cell-free DNA to Guide Analysis Strategy in Adult and Pediatric Solid Tumors. Poster presented at: Recent Advances in Circulating DNA & RNA. 10th Circulating Nucleic Acids in Plasma and Serum International Symposium; 2017 Sept 20-22; Montpellier, France.
5. **Cheng ML**, Yang JL, Shady M, Ulz P, Heitzer E, Socci N, Seshan V, Offin M, Stephens D, Makhnin A, Tandon N, Datta S, Gedvilaite E, Arcila ME, Ladanyi M, Chaft JE, Rudin CM, Berger MF, Solit DB, Li BT, Tsui DW. Non-Invasive Tumor Profiling in NSCLC by Targeted and Whole Exome Analysis of Plasma cfDNA. *J Thoracic Oncol* 12, 2017 (suppl; abstr OA 10.05). Oral Abstract, October 2017. IASLC World Conference on Lung Cancer; Yokohama, Japan. (Selected oral abstract presented by Tsui DW)
6. Jonsson P, **Cheng ML**, Bandlamudi C, Srinivasan P, Chavan SS, Friedman ND, Rosen EY, Richards AL, Bouvier N, Selcuklu SD, Bielski CM, Abida W, Zehir A, Schultz N, Donoghue MTA, Baselga J, Offit K, Ladanyi M, O'Reilly EM, Scher HI, Stadler ZK, Robson ME, Hyman DM, Berger MF, Solit DB, Taylor BS. BRCA-mediated tumorigenesis is origin and cell-type dependent. April 2019. AACR Annual Meeting; Atlanta, GA.
7. **Cheng ML**, Lau C, Milan MSD, Supplee JG, Riess JW, Bradbury PA, Paweletz CP, Oxnard GR. Response Assessment Using Plasma Cell-Free DNA (cfDNA) – When Is the Optimal Time to Assess Response? Poster Session, September 2019. IASLC World Conference on Lung Cancer; Barcelona, Spain.

Narrative Report

I am a clinical/translational investigator active in clinical investigation, translational research, patient care, institutional service, and training of students, fellows and physicians. These activities occur at DFCI as well as BWH, and flow mainly through my focus on thoracic malignancies and precision oncology. I dedicate 60% of my time towards clinical and translational research and 40% to patient care, primarily through my outpatient thoracic oncology clinic at DFCI.

My interest in academic oncology began during medical school and residency training, exemplified by an initial first author publication describing elevated esophageal cancer incidence in specific urban populations in Eastern Africa. My research focus coalesced around precision oncology during my fellowship, during which I leveraged large scale next-generation sequencing (NGS) data to elucidate cancer biology, with a special interest towards DNA damage response and repair (DDR) alterations. I was the second author of the largest analysis to characterize the uncommon phenotype of

microsatellite instability-high (MSI-H) or mismatch repair-deficient (dMMR) castrate resistant prostate cancer and demonstrate responses to immune checkpoint blockade, treatments which are ineffective in the overall prostate cancer population. I was the third author and lead clinical author (as the only MD among the first six authors) of an analysis studying the biologic relevance of BRCA mutations across cancer types in greater than 17,000 patients, which demonstrated that tumor lineage strongly dictates BRCA dependence, and these lineage-specific differences in turn define differential sensitivity to PARP inhibition.

I have applied this interest in precision oncology, especially with respect to DDR alterations and novel applications of NGS, towards my focus in thoracic malignancies as a faculty member. I am the co-senior author of the first analysis to demonstrate that deleterious DDR mutations are independently associated with improved clinical outcomes to PD-(L)1 immune checkpoint blockade in patients with non-small cell lung cancer (NSCLC). I am the overall principal investigator of a unique clinical trial which is the first to apply plasma genotyping-based response assessment to prospectively guide adaptive treatment of first-line treatment of NSCLC patients receiving immunotherapy. I have received several grants and awards including the Prostate Cancer Foundation Young Investigator Award and the American Society of Clinical Oncology Career (ASCO) Development Award, both three years in duration. I have presented at national and international meetings, including those held by the American Society of Clinical Oncology (ASCO) and International Association for the Study of Lung Cancer (IASLC).



Mickey Hu, MS, PhD

Dr. Mickey C. Hu has the expertise in antitumor immunity, breast cancer, cancer cell signaling, cancer immunotherapy, cancer metastasis, cell biology, cytotoxic T lymphocytes DNA damage, drug development, FOXO, immune checkpoints, immuno-oncology, immune suppressors, natural killer (NK) cells, ovarian cancer, p53, protein degradation, prostate cancer, reprogramming cancer cell, signaling mechanism, T cells, tumor microenvironment, tumor suppressors, and various cancers. He has served as Principal Investigator and Director of Discovery Oncology at the Panorama Institute of Molecular Medicine, Associate Professor at Stanford University School of Medicine, California.

Mickey C-T. Hu, M.S., Ph.D.

Director in discovery oncology/Principal Investigator - Panorama Institute of Molecular Medicine/Panorama Research Institute - 1230 Bordeaux Drive, Sunnyvale, CA 94089, USA

PROFILE

A self-driven and highly motivated research leader striving for excellent science and innovation with a passion of drug development for improving human health and life quality. Expert in translational oncology and immuno-oncology researches and with 15+ years of independent principal investigator experience in cancer research at Stanford University, etc.

CORE EXPERTISE/PROGRAM

- *Built a research team to develop therapeutic drugs, organized and supervised direct reports.*
- Developing novel therapeutic methods to overcome NK exhaustion, inhibitory networks in the tumor microenvironment (TME), and tumor-infiltration hurdles for establishing NK cell-based therapies (e.g., “off-the-shelf” CAR-NK therapy).
- Developing novel “scFv-split superantigen (SAg)” for cancer immunotherapy to overcome CD8⁺ T or NK cell exhaustion and boost cytotoxic T or NK cell responses in the TME.
- Developing novel mAbs that selectively block the interaction of the human integrin $\alpha\beta8$ with its ligand, latent TGF- $\beta1$ / $\beta3$ to enhance the antitumor immune response in the TME. Mature TGF- $\beta1$ / $\beta3$ are major secreted “immune blockers” in the blood.
- Developing novel immunomodulatory drugs to target cellular “immune blockers” (e.g., CBL-B) to promote TAM receptors (TYRO3, AXL, and MER) expressions in cytotoxic T or NK cells in the TME or promoting “off-the-shelf” CAR-NK cells.
- Adult stem cell reprogramming and hormonal therapy for cancer associated lymphedema (and interested in adult stem cell reprogramming for human regenerative medicine).
- Reprogramming cancer stem cells (various cancers) into non-cancerous cells.
- Developing pharmacological drugs or monoclonal antibody (mAb) drugs or Fc- or albumin (ALB)-fusion engineered protein drugs as tumor immunotherapy for treating cancers.

PROFESSIONAL EXPERIENCE

Panorama Institute of Molecular Medicine/Panorama Research Institute

Director and Principal Investigator (equivalent to Professor) 6/2017 – present Sunnyvale, CA

- Served as Director and Principal Investigator in discovery oncology
- *Built a research team to develop therapeutic drugs, organized and supervised direct reports.*
- In collaboration with Drs. J. Larrick and B. Yu (PRI) and Dr. R. Jerala, we are developing scFv-split SAg for cancer immunotherapy to overcome CD8⁺ T or NK cell exhaustion in TME. To solve the problems of conventional antibody–SAg fusion proteins, we have split SAg into two fragments that are individually inactive, until both fragments come into proximity and reassemble into a biologically active form capable of activating cytotoxic T or NK cell responses, and that do not spontaneously reassemble into an active form.
- Targeting metastatic breast cancer and ovarian cancer with novel metastasis-inhibiting drugs.
- Cancer immunotherapy is often negatively regulated by “endogenous immune blockers” in cytotoxic T or NK cells other than immune-checkpoints. Deciphering the key mechanisms by which the “endogenous immune blockers” (e.g., TGF- β , Cbl-b) inhibit cytotoxic T lymphocytes (CTL) or NK cell immune responses against tumors.
- Developing novel therapeutic drugs to target immune blocker to boost CTL or NK cell immune responses against tumors.
- Discovered, first to develop, identified FOXO3 protein which was shown to be essential for pharmacological drug-promoted anti-tumor immunity in tumor microenvironment.

- Developed the FOXO3-based screen for small molecules or biotherapeutics as a drug discovery platform to identify novel anticancer or cancer immunomodulatory drugs.
- Overcoming cancer-associated lymphedema with adult stem cell reprogramming and novel engineered hormonal proteins and/or nanoparticle therapies.
- Managed multiple projects that resulted in patent application filing for cancer therapeutics.

Stanford University Medical Center

Associate Professor (University tenure line) 9/2008 – 6/2017 *Stanford, California*

- Served as Associate Professor in the Division of Gynecologic Oncology
- *Built a research team to develop anticancer drugs, organized and supervised direct reports.*
- Managed a few projects that resulted in patent application filing for cancer therapeutics
- Awarded STTR grant for novel therapies for treating cancer related lymphedema (swelling in an arm or leg caused by a lymphatic system blockage)
- Awarded Avon breast cancer grant for targeting metastatic breast cancer with novel metastasis-inhibiting drugs
- Interested in developing immune receptor blockades by protein or Ab engineering
- Awarded NCI grant for overcoming cancer linked lymphedema with adult stem cell-hormone therapy
- Discovered, first to develop, identified the FOXO3 gene which was shown to be essential for pharmacological drug-mediated tumor suppression
- Discovered, first to develop, identified FOXO3 protein which was shown to be essential for pharmacological drug-induced cancer cell reprogramming
- Developed the FOXO3-based screen for small molecules as a drug discovery platform to identify novel anticancer or immuno-oncology pharmacological drugs
- Works published in Nature Cell Biology 2008, Nature Communications 2012, Scientific Reports 2014, and Oncotarget 2016

University of Texas M.D. Anderson Cancer Center

Assistant Professor (NTRA and tenure-track) 3/1999 – 8/2008 *Houston, Texas*

- Served as Assistant Professor in the Department of Molecular & Cellular Oncology, and the Department of Cancer Biology
- *Built a research team to develop anticancer drugs, organized and supervised direct reports.*
- Discovered, first identified FOXO3 protein which was shown to be a key tumor suppressor
- Discovered, first identified FOXO3 which was shown to be a key regulator in ionizing radiation-induced cancer cell death
- Work published in Cell 2004
- Awarded NCI R01 5-year grant for studying the role of regulation of FOXO3a in tumor suppression
- Awarded DOD USAMRMC Breast Cancer Research grant for targeting breast cancer with a novel tumor-specific drug
- Discovered, first developed a novel tumor-specific neurotropic peptide-toxin for overcoming malignant breast cancer

Amgen Research Center, Amgen Inc.

Principal Investigator 7/1992 – 2/1999 *Thousand Oaks, California*

- Served as Principal Investigator in the Departments of Experimental Hematology and Functional Genomics
- *Built a research team to develop protein drugs, organized and supervised direct reports.*

- Was part of the team that developed a megakaryocyte growth and development factor
- Built the first IgG-Fc fusion engineered proteins, and discovered and first isolated the human HPK1 gene which was shown to be a novel human hematopoietic progenitor kinase that activates the JNK/SAPK kinase cascade in response to stress.
- Discovered, first demonstrated that JNK kinases regulate p53 tumor suppressor and protein phosphatase X activates c-Rel/NF- κ B.
- Discovered, first isolated the FGF-18, a novel member of the fibroblast growth factor family, stimulates hepatic and intestinal proliferation, and p38- δ MAPK which was shown to be activated by stress and proinflammatory cytokines.
- Discovered, first demonstrated that the cytoplasmic domain of stem cell antigen CD34 is essential for cytoadhesion signaling in hematopoietic cells.
- Works published in Cell 1994, Genes and Development 1996, Blood 1998, Oncogene 1997 and 1999, Molecular and Cellular Biology 1998, and Journal of Biological Chemistry 1998 and 1999.

Postdoctoral Research Fellow

California Institute of Technology, Division of Biology, Pasadena, CA, Mentor: Dr. **Norman Davidson**, 6/1988 – 5/1989

- Discovered, first developed a combination of de-repression of the *lac* operator-repressor system with positive induction by glucocorticoid and metal ions in mammalian cells
- Work published in Molecular and Cellular Biology 1990

Stanford University Medical Center, Department of Pathology, Stanford, CA, Mentor: Dr. **Irving L. Weissman**, 6/1989 – 7/1992

- Discovered, first made an antibody against the β chain of Peyer's patch homing receptor, integrin $\alpha 4/\beta 7$, first isolated and cloned $\beta 7$ receptor by expression cloning with $\beta 7$ antibody
- First documented that the expression of integrin $\alpha 4/\beta 7$ in lymphocytes played a key and essential role in regulating lymphocyte migration and binding to the gut Peyer's patches
- Work published in Proc Natl Acad Sci USA 1992 and Journal of Cell Biology 1991
- Strikingly, this $\alpha 4/\beta 7$ receptor has been highlighted as a novel receptor for HIV entry through the gut (Nature Immunology 2008), and a key target for AIDS therapy.

EDUCATION

Graduate Student/Doctoral Research Scientist

Ph.D. degree: I obtained my Ph.D. degree from *California Institute of Technology* in Chemical Biology & Molecular Biology, Mentor: Dr. **Norman Davidson**, 9/1983 – 5/1988, Ph.D. Thesis Title: The inducible *lac* operator-repressor system is functional in mammalian cells.

- Discovered, first developed a novel inducible promoter, a **genetic switch**, in mammalian cells by using the *lac* repressor-operator system
- Works published in Cell 1987, and Gene 1988 and 1991
- First isolated and characterized the mouse skeletal α -actin gene
- Works published in Molecular and Cellular Biology 1986, and Gene 1986

M.S. degree: from National Taiwan University, Biochemical Sciences, 9/1980 – 6/1982, graduation with honor (Mentor: Dr. Yee-Hsiung Chen)

B.S. degree: from National Taiwan University, Chemistry, 9/1974 – 6/1978

Army Chemical School (Taiwan), Nuclear Chemistry & Biology (compulsory military training)

and service for two years), 7/1978 – 6/1980

Awards

Graduate Scholarship, California Institute of Technology, 1983-1988

Li-Ming Outstanding Research Award, Los Angeles, 1988

The Herbert Newby McCoy Award, Caltech, 1988

Postdoctoral Research Fellowship, Amgen, Inc., 1988-1989

Leukemia Society of America Postdoctoral Fellowship, 1989-1992

Howard Hughes Medical Institute Postdoctoral Fellowship, 1992-1993

RESEARCH GRANTS

Funded:

Active Research Support:

1. Principal Investigator, Targeting metastatic breast cancer with novel EMT-inhibiting drugs, the 2017 Avon Breast Cancer Crusade Research Program Award, Grant #02-2017-067, 12/01/17-8/31/20
2. Principal Investigator, Stem cell-adrenomedullin therapy for cancer linked lymphedema, NIH/NCI 1R21CA201940-01A1, 09/01/16-07/31/20
3. Principal Investigator, Novel hormonal therapeutics for diabetic impaired wound healing, DOD FY19 Peer Reviewed Medical Research Program Discovery Award, PR192588, 02/01/20-01/31/22 (Recommended For Funding, see an attached letter from DOD)

Pending:

1. Principal Investigator, Development of novel therapeutic approaches for improving resistant hypertension and cardio-myopathy, DOD FY19 Peer Reviewed Medical Research Program Discovery Award, PR192595, 02/01/20-01/31/22 (Recommended As An Alternate)
2. Principal Investigator, Boosting pancreatic cancer immunotherapy by inhibiting killer T cell immune suppressors, NIH/NCI GRANT12883225 (1R03), 05/01/20-04/31/22
3. Principal Investigator, Effective Combination Approaches for Lymphedema, NIH/NCI GRANT12931903 (1R43, SBIR), 07/01/20-06/30/21
4. Principal Investigator, Novel anti-FOLR1 and anti-TROP2 therapies for ovarian cancer, NIH/NCI GRANT12929451 (1R43, SBIR), 07/01/20-06/30/21
5. Principal Investigator, Suppressing kidney cancers by targeting TGF- β 1 and - β 3 activation for boosting cancer immunotherapy, DOD USAMRMC FY19 Kidney Cancer Research Program Idea Development Award, GRANT12942920, 07/01/20-06/30/22
6. Principal Investigator, Targeting TROP-2 on metastatic breast cancer with novel immunomodulatory drugs for boosting cancer immunotherapy, DOD USAMRMC FY19 Breast Cancer Research Program Breakthrough Award BTA12-2, GRANT12927883, 07/01/20-06/30/23

Completed Research Support:

1. Principal Investigator, Developing innovative therapies against breast and ovarian cancers, the Fini Women's Cancer grant and the Freidenrich Center for Translational Research, Stanford Women's Cancer Center, #1170149, 09/01/14-06/01/17
2. Principal Investigator, Examining combinations of environmental carcinogen exposures in the development of breast cancer, Avon Foundation for Women, Grant# 02-2014-046, 10/01/14-09/30/16.
3. Principal Investigator (dual principal investigators with Dr. S. Hsu), Developing Novel Therapies for Treating Breast Cancer Related Lymphedema, NIH/NCI 1R41CA183335-01, 10/01/14-12/31/15
4. Principal Investigator, Exposure to tobacco smoke and BPA together augments the risk of

- developing breast cancer, Avon Foundation for Women, Grant# 02-2013-051, 10/01/13-09/31/14
5. Principal Investigator, The Role of Regulation of FOXO3 in Tumor Suppression, NIH/NCI 7 R01CA113859, 02/01/06-12/30/13
 6. Principal Investigator, Activation of FOXO tumor suppressor for triple-negative breast cancer therapy, Stanford Cancer Institute (Developmental Cancer Research Award), 09/01/12-08/31/13
 7. Mentor, The Ann Schreiber Research Training Programs of Excellence (the Ovarian Cancer Research Fund), Park (PI), Targeting Ovarian Cancer with Combination of Olaparib and Bepridil, 3/1/12-2/28/13
 8. Principal Investigator, Roles of BPA and FOXO in DNA damage response in breast cancer development, Avon Foundation for Women, Grant# 02-2010-063, 07/01/10-06/30/12
 9. Mentor, The Rivkin Center Scientific Scholar Award by Marsha Rivkin Center, Chung (PI), Targeting Ovarian Cancer with Combination of Olaparib and Trifluoperazine, 4/1/2011-3/31/2012
 10. Co-Principal Investigator, Bone Metastasis Factor-1 in Prostate Cancer/Bone Interaction, NIH/NCI 1R01CA111479-01A1, Lin (PI), 07/01/05-4/30/10
 11. Principal Investigator, Activation of FOXO tumor suppressor for breast cancer therapy and prevention, The Susan G. Komen Breast Cancer Foundation BCTR0504415, 05/01/05-12/31/09
 12. Principal Investigator, Targeting malignant breast cancer cells with a tumor-specific neurotropic peptide-toxin, DOD USAMRMC Breast Cancer Research Program Concept Award BC045295, 09/01/05-08/31/08
 13. Principal Investigator, FOXO Signaling in DNA Damage and Repair Responses. The Texas Advanced Research Program, ARP grant, 09/01/06-08/30/08
 14. Investigator, Targeting Breast Cancer with FOXO Therapy, Development Research Award, P50 CA116199-01 Breast SPORE, Hortobagyi (PI), 06/01/05-51/31/07
 15. Co-Investigator, The Functional Analysis of the Coactivator CARM1, NIH/ NIDDK R01 DK62248-01, Bedford (PI), 07/01/02-06/30/07
 16. Principal Investigator, Cyclin D1 as a therapeutic target in human breast cancer, The Susan G. Komen Breast Cancer Foundation BCTR0201848, 05/01/03-04/30/06
 17. Principal Investigator, Assessing Functional Estrogen Receptors in Primary and Metastatic Breast Cancers in vivo with ^{99m}Tc-labeled Estradiol. MDACC Institutional Research Grant, 02/01/03-01/31/04
 18. Principal Investigator, The Hormone-Unresponsive Disease of Estrogen Receptor in Breast Cancer, Pharmacia (formerly Monsanto) Research Grant SR00-203-1, 07/01/00-06/30/02
 19. Principal Investigator, CCSG Developmental Fund in Breast Cancer, UT MDACC, 06/01/01-05/31/02

PUBLICATIONS

- A. Selected Peer-Reviewed Journals:** (56 published, 1 be submitted, and 4 in preparation)
1. Lin, K.C., Lin, Y.S., and **Hu, M.C.** (1981). Graftcopolymerization of methyl methacrylate onto bamboo using infrared spectroscopic technique as a probe. *Proc. Natl. Sci. Counc.B, ROC* **5**:26-30.
 2. Chen, Y.-H., **Hu, M.C.**, and Yang, J.T. (1984). Membrane disintegration and hemolysis of human erythrocytes by snake venom cardiotoxin (a membrane-disruptive polypeptide). *Biochem. Int.* **8**:329-338.
 3. Chen, Y.-H., Liou, R.-F., **Hu, M.C.**, Juan, C.-C., and Yang, J.T. (1987). Interaction of snake venom cardiotoxin (a membrane-disruptive polypeptide) with human erythrocytes. *Mol. Cell. Biochem.* **73**:69-76.

4. **Hu, M.C.**, Sharp, S.B., and Davidson, N. (1986). The complete sequence of the mouse skeletal α -actin gene reveals several conserved and inverted repeat sequences outside of the protein-coding region. *Mol. Cell. Biol.* **6**:15-25.
5. **Hu, M.C.** and Davidson, N. (1986). Mapping transcription start points on cloned genomic DNA with T4 DNA polymerase: a precise and convenient technique. *Gene* **42**:21-29.
6. **Hu, M.C.** and Davidson, N. (1987). The inducible *lac* operator-repressor system is functional in mammalian cells. *Cell* **48**:555-566. (Total citation > 245 times)
7. **Hu, M.C.** and Davidson, N. (1988). The inducible *lac* operator-repressor system is functional for control of expression of injected DNA in *Xenopus* oocytes. *Gene* **62**:301-313.
8. **Hu, M.C.** and Davidson, N. (1990). A combination of derepression of the *lac* operator-repressor system with positive induction by glucocorticoid and metal ions provides a high-level-inducible gene expression system based on the human metallothionein-IIA promoter. *Mol. Cell. Biol.* **10**:6141-6151.
9. **Hu, M.C.** and Davidson, N. (1991). Targeting the *Escherichia coli lac* repressor to the mammalian cell nucleus. *Gene* **99**:141-150.
10. Neuhaus, H., **Hu, M.C.**, Hemler, M.E., Takada, Y., Holzmann, B., and Weissman, I.L. (1991). Cloning and expression of cDNAs for the α subunit of the murine lymphocyte-Peyer's patch homing receptor: Homology to the human integrin α 4 subunit and other integrins. *J. Cell Biol.* **115**:1149-1158.
11. **Hu, M.C.**, Crowe, D.T., Holzmann, B., and Weissman, I.L. (1992). Cloning and expression of mouse integrin β p(β 7): a functional role in Peyer's patch-specific lymphocyte homing. *Proc. Natl. Acad. Sci. USA* **89**:8254-8258. (Total citation > 182 times)
12. Bartley, T.D., Bogenberger, J., Hunt, P., Li, Y.S., Lu, H.S., Martin, F., Chang, M.S., Samal, B., Nichol, J.L., Swift, S., Johnson, M.J., Hsu, R.Y., Parker, VP, Suggs, S, Skrine, JD, Merewether, LA, Clogston, C, Hsu, E, Hokom, MM, Hornkohl, A, Choi, E, Pangelinan, M, Sun, Y, Mar, V, Mchinch, J, Simonet, L, Jacobsen, F, Xie, C, Shutter, J, Chute, H, Basu, R, Selander, L., Trollinger, D., Sieu, L., Padilla, D., Trail, G., Elliott, G., Izumi, R., Covey, T., Crouse, J., Garcia, A., Xu, W., Delcastillo, J., Biron, J., Cole, S., **Hu, M.C.**, Pacific, R., Ponting, I., Saris, C., Wen, D., Yung, Y.P., Lin, H., Bosselman, R.A. (1994). Identification and cloning of a megakaryocyte growth and development factor that is a ligand for the cytokine receptor *mpl*. *Cell* **77**:1117-1124.
13. Hailman, E., Vasselon, T., Kelley, M., Busse, L.A., **Hu, M.C.**, Lichenstein, H.S., Detmers, P.A., and Wright, S.D. (1996). Stimulation of macrophages and neutrophils by complexes of lipopolysaccharide and soluble CD14. *J. Immunol.* **156**:4384-4390.
14. **Hu, M.C.**,* Qiu, W.R., Wang, X., Meyer, C.F., and Tan, T.-H.* (1996). Human HPK1, a novel human hematopoietic progenitor kinase that activates the JNK/SAPK kinase cascade. *Genes Dev.* **10**:2251-2264. [*co-corresponding] (Total citation > 233 times)
15. Wang, W., Zhou, G., **Hu, M.C.**, Yao, Z., and Tan, T.-H. (1997). Activation of the hematopoietic progenitor kinase-1 (HPK1)-dependent, stress-activated c-Jun N-terminal kinase (JNK) pathway by transforming growth factor β (TGF- β)-activated kinase (TAK1), a kinase mediator of TGF- β signal transduction. *J. Biol. Chem.* **272**:22771-22775.
16. **Hu, M.C.**,* Qiu, W.R., and Wang, Y. (1997) JNK1, JNK2 and JNK3 are p53 N-terminal serine 34 kinases. *Oncogene* **15**:2277-2287. [*corresponding]
17. **Hu, M.C.**,* and Chien, S.L. (1998). The cytoplasmic domain of stem cell antigen CD34 is essential for cytoadhesion signaling but not sufficient for proliferation signaling. *Blood* **91**:1152-1162. [*corresponding]
18. **Hu, M.C.**,* Qiu, W.R., Wang, Y., Hill, D., Ring, B., Scully, S., Bolon, B., DeRose, M., Luethy, R., Simonet, W.S., Arakawa, T. and Danilenko, D. (1998). FGF-18, a novel member of the fibroblast growth factor family, stimulates hepatic and intestinal

- proliferation. *Mol. Cell. Biol.* **18**:6063-6074. [*corresponding]
19. **Hu, M.C.,*** and Wang, Y. (1998). I κ B kinase- α and - β genes are coexpressed in adult and embryonic tissues but localized to different human chromosomes. *Gene* **222**:31-40.
 20. **Hu, M.C.,*** Tang-Oxley, Q., Qiu, W.R., Wang, Y., Mihindikulasuriya, K.K., Afshar R., and Tan, T.-H.* (1998). Protein phosphatase X interacts with c-Rel and stimulates c-Rel/NF- κ B activity. *J. Biol. Chem.* **273**:33561-33565. [*corresponding]
 21. **Hu, M.C.,*** Wang, Y., Mikhail, A., Qiu, W.R., Tan, T.-H.* (1999). Murine p38- δ mitogen-activated protein kinase, a developmentally regulated protein kinase that is activated by stress and proinflammatory cytokines. *J. Biol. Chem.* **274**:7095-7102. [*co-corresponding]
 22. **Hu, M.C.,*** Wang, Y., and Qiu, W.R. (1999). Human fibroblast growth factor-18 stimulates fibroblast cell proliferation and is mapped to chromosome 14p11. *Oncogene* **18**:2635-2642.
 23. **Hu, M.C.,*** Wang, Y., Qiu, W.R., Mikhail, A., Meyer, C.F., and Tan, T.-H.* (1999). Hematopoietic progenitor kinase-1 (HPK1) stress response signaling pathway activates I κ B kinases (IKK- α/β) and IKK- β is a developmentally regulated protein kinase. *Oncogene* **18**:5514-5524. [*co-corresponding]
 24. Shih, C-C., **Hu, M.C.,** Hu, J., Medeiros, J., and Forman, S.J. (1999). Long-term *ex vivo* maintenance and expansion of transplantable human hematopoietic stem cells. *Blood* **94**:1623-1636.
 25. Shih, C-C., **Hu, M.C.,** Hu, J., Weng, Y., Yazaki, P.J., Medeiros, J., and Forman, S.J. (2000). A secreted and LIF-mediated stromal cell-derived activity that promotes *ex vivo* expansion of human hematopoietic stem cells. *Blood* **95**:1957-1966.
 26. Shao, R.,* **Hu, M.C.,*** Zhou, B.P., Lin, S-Y., Chiao, P.J., von Lindern, R.H., Spohn, B., and Hung, M.-C. (1999). E1A sensitizes cells to tumor necrosis factor-induced apoptosis through inhibition of I κ B kinases and nuclear factor- κ B activities. *J. Biol. Chem.* **274**:21495-21498. [*equal contribution]
 27. Zhou, B.P., **Hu, M.C.,** Miller, S., Yu, Z., Xia, W., Lin, S-Y., and Hung, M.-C. (2000). HER-2/*neu* blocks tumor necrosis factor-induced apoptosis via the Akt/NF- κ B pathway. *J. Biol. Chem.* **275**:8027-8031.
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 29. Wen, Y.,* **Hu, M.C.,*** Makino, K., Bartholomeusz, G., Spohn, B., Yan D-H., and Hung, M.-C. (2000). HER-2/*neu* promotes androgen-independent survival and growth of prostate cancer cells through the Akt pathway. *Cancer Res.* **60**:6841-6845. [*Equal contribution] (Total citation > 506 times)
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36. **Hu, M.C.**,* Lee, D-F., Xia, W., Golfman, L., Ou-Yang, F., Yang, J-Y., Zou, Y., Bao, S., Hanada, N., Saso, H., Kobayashi, R., and Hung, M.-C.* (2004). IκB kinase promotes tumorigenesis through inhibition of Forkhead FOXO3a. *Cell* **117**:225-237. [*co-corresponding] (Total citation > **894** times).
 - *Featured in 2004 June Issue of Nature Reviews Cancer Research Highlight "Tumorigenesis: Right place, wrong time"*.
 - *Featured in 2004 April Issue of Science STKE Editors' Choice "IKK: Another Path to FOXO inhibition"*.
37. Yang, J-Y., Xia, W., and **Hu, M.C.*** (2006). Induction of FOXO3a and Bim expression in response to ionizing radiation. *Int. J. Oncology* **29**:643-648. [*corresponding]
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39. Shui, J.-W., **Hu, M.C.**, and Tan, T.-H. (2007). Conditional knockout mice reveal an essential role of protein phosphatase 4 in thymocyte development and pre-TCR signaling. *Mol. Cell. Biol.* **27**:79-91.
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41. Zou, Y., Tsai, W.B., Cheng, C-J., Hsu, C., Chung, Y.M., Li, P.C., Lin, S-H., and **Hu, M.C.*** Forkhead box transcription factor FOXO3a suppresses estrogen-dependent breast cancer cell proliferation and tumorigenesis. *Breast Cancer Res.* 2008 Feb 29;10(1):R21. [*corresponding]
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43. Chu, K., Cheng, C-J., Ye, X-C., Lee, Y-C., Zurita A., Chen, D.-T., Yu-Lee, L.-Y., Yeh, E., **Hu, M.C.**, Logothetis, C. J., and Lin, S.-H. (2008). Cadherin-11 promotes the metastasis of cancer cells to bone. *Mol. Cancer Res.* **6**:1259-1267.
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- Mann, M., Ciechanover, A., Dahm-Daphi, J., Kanaar, R., **Hu, M.C.**, Chen, D.J., Oren, M., and Shiloh, Y. (2011). Requirement of ATM-dependent monoubiquitylation of histone H2B for timely repair of DNA double-strand breaks. *Mol. Cell* **41**(5):529-542.
48. Segal-Raz, H., Mass, G., Baranes-Bachar, K., Lerenthal, Y., Wang, S.-Y., Chung, Y.M., Ziv-Lehrman, S., Ström, C.E., Helleday, T., **Hu, M.C.**, Chen, D.J., and Shiloh, Y. (2011). ATM-mediated phosphorylation of polynucleotide kinase/phosphatase (PNKP) is required for effective DNA double-strand break repair. *EMBO Rep.* **12**(7):713-719.
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 52. Hu, T., Chung, Y.M., Guan, M., Ma, M., Ma, J., Berek, J.S., and **Hu, M.C.*** (2014). Reprogramming ovarian and breast cancer cells into non-cancerous cells by low-dose metformin or SN-38 through FOXO3 activation. *Sci. Rep. (Nature)* **4**:5810 [*corresponding]
 53. Park, S.H., Lee, J.-H., Berek, J.S., and **Hu, M.C.*** (2014). Anticancer activity of Auranofin against ovarian cancer cells through the activation of FOXO3. *Int. J. Oncol.* **45**: 1691-1698.
 54. Chen, M.-C., Zhou, B., Yuan, Y.-C., Un, F., Hu, S., Chou, C.-M., Wu, J., Wang, Y., Liu, X., Smith, D.L., Li, H., Warden, C.D., Su, L., Malkas, L.H., Chung, Y.M., Zhang, K.-Q., **Hu, M.C.**, and Yen, Y. (2015). The novel ribonucleotide reductase inhibitor COH29 inhibits DNA repair in vitro. *Mol. Pharmacol.* **87**: 996-1005.
 55. Pfeifer, D., Chung, Y.M., and **Hu, M.C.*** (2015). Effects of Low-Dose Bisphenol A on DNA Damage and Proliferation of Breast Cells: The Role of c-Myc. *Environ. Health Perspect.* **123**: 1271-1279. [*corresponding] (*This Journal is #3 in all Public Health Journals*) @Featured in 2015 December Issue of News/Science Selections. "Examining BPA's Mechanisms of Action: The Role of c-Myc." *Environ Health Perspect.* 2015 Dec 1;123(12):A304. (citation > 73 times)
 56. Park, S.H., Chung, Y.M., Ma, J., Yang, Q., Berek, J.S., and **Hu, M.C.*** (2016). Pharmacological activation of FOXO3 suppresses triple-negative breast cancer *in vitro* and *in vivo*. *Oncotarget* **7**: 42110-42125 (2016). [*corresponding]

B. Manuscripts Be Submitted or In Preparation:

1. Chung, Y.M., Khan, P.P., Wang, H., Tsai, W.B., Qiao, Y., Yu, B., Larrick, J.W., and **Hu, M.C.*** Enhancing anti-PD-1 efficacy by pharmacological activation of FOXO3 in tumors and recruiting NK or CD8+ T cells. *Commun. Biol.* 2020, submitted [*corresponding]
2. Chung, Y.M., Park, S.H., Ma, J., Berek, J.S., and **Hu, M.C.*** Inhibitions of PARP1 and TOP1 in ovarian tumors suppress tumor drug resistance via FOXO3 activation. (in preparation) [*corresponding]
3. Khan, P.P., Chen, H.H., Ma, J., Chung, Y.M., Yu, B., Larrick, J.W., and **Hu, M.C.*** Novel regenerative therapy for cancer associated lymphedema with the calcitonin receptor-like receptor agonist. (in preparation) [*corresponding]
4. Chung, Y.M., Ma, J., Tsai, W.B., Chen, C.-S., Berek, J.S., and **Hu, M.C.*** Activation of FOXO3 by curcumin, Bortezomib, and OSU-03012 for triple-negative breast cancer therapy. (in preparation) [*corresponding]
5. Chung, Y.M., Zou, Y., Park, S.H., Tsai, W.B., Xu, Z., Berek, J.S., and **Hu, M.C.*** Targeting

ovarian and breast cancer cells with a tumor-specific neurotropic peptide-toxin. (in preparation) [*corresponding]

C. Invited Review Journals and Book Chapters:

1. **Hu, M.C.**, Holzmann, B., Neuhaus, H., and Weissman, I.L. (1991). The Peyer's patch homing receptor: A novel member of the integrin family. In: Cochrane C.G. and Gimbrone Jr., M.A., eds. *Cellular and Molecular Mechanisms of Inflammation: Vascular Adhesion Molecules*. Vol. 2. San Diego: Academic Press, pp. 91-110.
2. **Hu, M.C.**, Siegelman, M.H., Holzmann, B., Crowe, D.T., Neuhaus, H., and Weissman, I.L. (1992). Lymphocyte homing receptors. *Cold Spring Harbor Symp. Quant. Biol.* **57**:291-308.
3. **Hu, M.C.**, Holzmann, B., Crowe, D.T., Neuhaus, H., Weissman, I.L. (1993). The Peyer's patch homing receptor. *Current Topics in Microbiology and Immunology* **184**:125-138.
4. **Hu, M.C.** and Davidson, N. (1993). Mapping transcription start points with T4 DNA polymerase. In: Wu, R., ed. *Methods in Enzymology: Recombinant DNA*. Florida: Academic Press, **217**:446-458.
5. Hung, M.-C. and **Hu, M.C.** (2000) Basic science of HER-2/*neu*: a review. *Physicians' Education Resource-HER2 in Oncology* **1**:5-8.
6. **Hu, M.C.**, Xia, W., and Hung, M.-C. (2001) Maspin, a potential prognostic marker for human cancers. In: Hendrix, M. J. ed. "Maspin". Georgetown: RG Landes Co., 2001.
7. **Hu, M.C.**, and Hung, M.-C. (2005) Role of I κ B kinase in tumorigenesis. *Future Oncology* **1**:67-78.

PATENTS

1. Invention No. S14-454: Hu, M.C., Chung, Y.M., and Berek, J.S. A Small-Molecule Approach for Cancer Immunotherapy. (Stanford University), pending
2. Invention No. S12-202: Hu, M.C., Chung, Y.M., and Berek, J.S. Cancer Therapy with PARP Inhibitors and FOXO3 Activating Small Molecules. (Stanford University), pending

COMMITTEE MEMBERSHIPS

Grant Review Study Sections:

- 2000 DOD USAMRMC CDMRP, 2000 Breast Cancer Research Program Review Panel: Clinical and Experimental Therapeutics-4
- 2004 DOD USAMRMC CDMRP, 2004 Breast Cancer Research Program Review Panel: Concept Award
- 2004 DOD USAMRMC CDMRP, 2004 Prostate Cancer Research Program Review Panel: Clinical and Experimental Therapeutics-2
- 2004 DOD USAMRMC CDMRP, 2004 Breast Cancer Research Program Review Panel: Pathobiology-3.
- 2005 DOD USAMRMC CDMRP, 2005 Breast Cancer Research Program Review Panel: Pathobiology-2.
- 2007 Breast Cancer Campaign, London EC2A 4HT, UK, Ad Hoc Reviewer
- 2007 Center for Targeted Therapeutics, Neuro Pilot Projects, M. D. Anderson Cancer Center, Ad Hoc Reviewer
- 2008 DOD USAMRMC CDMRP, 2008 Breast Cancer Research Program Concept Award Review Panel, CET-5
- 2008 Center for Targeted Therapeutics, Lymphoma/Myeloma, UT-M.D. Anderson Cancer Center, Ad Hoc Reviewer
- 2009-2010 DOD USAMRMC CDMRP, 2009 and 2010 BCRP Concept Award Review Panel, BCRP IDEA Award PBY-3 Review Panel, and PCRPR PRE-PBY-B Review Panel.
- 2009 NIH RFA OD-09-003 Challenge Grants Panel 10.

2009 NIH Challenge Grants in Health and Science Research (RC1)-hESC Review Panel
 2010 Susan G. Komen for the Cure Postdoctoral Fellowship peer review committees
 2011 NIH Grant Review Panel, 2011/05 ZRG1 IMM-G (03) (Immunology) M Scientific Review Group (SRG)
 2012 DOD USAMRMC CDMRP FY12 BCRP Review Panel: Impact Award
 2012-2013 DOD USAMRMC CDMRP FY13 BCRP Review Panel: Training 2-Cell Biology
 2013 DOD USAMRMC CDMRP FY13 BCRP Review Panel: Cell and Molecular Biology
 2014 DOD USAMRMC CDMRP FY14 BCRP Review Panel: Cell Biology
 2015, 2018 DOD CDMRP FY15 BCRP Breakthrough_FL1/2 Award Review Panel: Cell Biology, W81XWH-15-OCRP-IIRA, and W81XWH-18-BCRP-BTA12_IMM-1 review Panel.
 2015-2018 NIH Grant, the Cancer Drug Development & Therapeutics (CDDT) study section
 2016 NIH Grant, the Special Emphasis Panel 2016/10 ZCA1 SRB-J (O1) S study section
 2017 the Cancer Prevention Research Institute of Texas (CPRIT) RES 17.2 C/TCR and CPRIT RES 18.1 C/TCR
 2018 DOD BCRP BC18.1 IMM-1, and CPRIT RES 18.2 C/TCR and CPRIT RES 19.1 C/TCR
 2019 CPRIT RES 19.2 C/TCR, DOD BCRP_BC19.1 IMM-1, and CPRIT RES 20.1 C/TCR
 2020- CPRIT RES 19.2 C/TCR, CPRIT RES 20.1 C/TCR, CPRIT RES 20.2 C/TCR, etc.

Publication Reviewer:

2000-present, Invited journal reviewer for American Journal of Pathology, Cancer Research, Clinical Cancer Research, Oncogene, Journal of Biological Chemistry, Molecular and Cellular Biology, International Journal of Cancer, International Journal of Gynecological Cancer, PLoS One, Oncogene, Oncotarget, Scientific Reports, etc.

Editorial Board:

2015-present **Editorial Board Member** (editor), *Scientific Reports* (Nature Publishing Group)

Committee Member:

2000-2003 Senator of Faculty Senate at UT-M.D. Anderson Cancer Center
 2010-2016 The Stanford Cancer Center Scientific Review Committee (SRC) member.

CITIZENSHIP

United States of America

PRESENTATIONS

Presentations at National or International Conferences

2004 The Role of FOXO in Breast Cancer: Pathways to Drug Discovery, Mission Conference, The Susan G. Komen Breast Cancer Foundation, New York, 2004
 2006 The Role of FOXO Tumor Suppressor in Breast Cancer, 9th Annual Mission Conference, Susan G. Komen Breast Cancer Foundation, Washington, D.C., 2006
 2008 Targeting malignant breast cancer cells with a tumor-specific neurotropic peptide-toxin, The 16th Era of Hope Breast Cancer Meeting Poster, the DOD Breast Cancer Research Program Meeting, Baltimore, Maryland, June 25-28, 2008
 2013 Breast cancer, environmental factors, and your health, The 21st Annual National Conference of alpha Kappa Delta Phi Sorority, Santa Clara, California, May 26, 2013
 2013 FOXO3 and Out-FOXing Cancer: Pathways to Drug Discovery, Taipei Medical University, Taipei, Taiwan, 5/14/2013 (an invited lecturer)
 2014 FOXO3 and out-FOXing cancer: pathways to drug discovery, 19th World Congress on Advances in Oncology 9-11 October, 2014, Athens, Greece (an invited lecturer)

Other Institutions and Local Conferences

- 2004 Out-FOXing Cancer by FOXO: Pathways to Drug Discovery, Department of Molecular and Cellular Oncology, UT MD Anderson Cancer Center, Houston, Texas, 6/30/2004
- 2004 The Role of FOXO in Breast Cancer: Pathways to Drug Discovery, GU Medical Oncology Seminar Series, Department of GU Medical Oncology, UT MD Anderson Cancer Center, Department of GU Medical Oncology, Houston, Texas, 11/2/2004
- 2005 Role of Regulation of FOXO3a in Tumor Suppression, Department of Cancer Biology, MD Anderson Cancer Center, Department of Cancer Biology, Houston, Texas, 3/14/2005
- 2005 Roles of IKK and FOXO in Cancer: Pathways to Drug Discovery, Division of Johns Hopkins, Nanos, Nanos, Singapore, 4/27/2005
- 2007 The Role of FOXO3a in Tumor Suppression, Department of Biochemistry & Molecular Biology, UT Medical School, Houston, Texas, 2/21/2007
- 2007 The Role of FOXO Tumor Suppressor in Breast Cancer: Pathways to Drug Discovery, The Scripps Research Institute, Department of Cancer Biology, Jupiter, Florida, 4/12/2007
- 2007 The Role of FOXO Tumor Suppressor in Cancer: Pathways to Drug Discovery, Cancer Research Center of Hawaii, Department of Cancer Biology, Honolulu, Hawaii, 7/26/2007
- 2007 Roles of IKK and FOXO3 in Cancer: Pathways to Drug Discovery, Stanford University, Ob/Gyn and Stem Cell Institute, Stanford, California, 6/26/2007
- 2007 Role of FOXO Tumor Suppressor in Cancer: Pathways to Drug Discovery, John Hopkins University School of Medicine, Department of Oncology, Baltimore, Maryland, 8/20/2007
- 2007 The Role of FOXO Tumor Suppressor in Breast Cancer: Pathways to Drug Discovery, University of Miami, Sylvester Comprehensive Cancer Center, Miami, Florida, 10/26/2007
- 2008 FOXO3 in Tumor Suppression and DNA damage: Pathways to Drug Discovery, Dr. Weissman Montana Symposium 2008, NIAID, NIH, Montana, 7/23/2008
- 2010 Roles of IKK and FOXO3 in Cancer: Pathways to Drug Discovery, Stanford University, Ob/Gyn Research meeting, Stanford, California, 4/14/2010
- 2012 FOXO3 and Out-FOXing Cancer: Pathways to Drug Discovery, the Dr. Weissman Montana Symposium 2012, NIAID, NIH, Montana, 9/12/2012
- 2014 FOXO3 and out-FOXing cancer: pathways to drug discovery, Stanford University, Gynecologic Research Division meeting, Stanford, California, 10/6/2014
- 2016 Out-FOXing Cancer: Tumor Suppression, Reprogramming, and Immunity, Department of Pharmaceutical Sciences, South Dakota State University, Brookings, SD 57007, 4/11/2016
- 2016 Multifaceted therapeutic approaches: Tumor reprogramming and immunity, Department of Inflammation and Oncology, Amgen Inc., South San Francisco, CA, 5/25/2016
- 2016 Out-FOXing Cancer: Tumor Suppression, Reprogramming, and Immunity, Department of Cell Stress Biology, Roswell Park Cancer Institute in Buffalo, New York, 9/7/2016
- 2017 Out-FOXing cancer: cancer suppression, cancer immunity and reprogramming, Molecular Medicine Research Institute, Sunnyvale, CA 5/17/2017
- 2017 Boosting cancer immunotherapy with new immuno-pharmacology drugs, The Panorama Institute of Molecular Medicine/Panorama Research Institute, Sunnyvale, CA, 5/30/2017
- 2017 Out-FOXing cancer: tumor suppression and reprogramming, Taipei Medical University, Center for Cell Therapy and Regeneration Medicine, Taipei, Taiwan 11/16/2017

PROFESSIONAL MEMBERSHIPS

2000-present	American Association for Cancer Research
1999-2008	American Association for the Advancement of Science



Neil Vasan, MD, PhD

Neil Vasan is an Assistant Attending Physician on the Breast Medicine Service at Memorial Sloan Kettering Cancer Center. He is a physician-scientist working in the laboratory of Dr. Lewis Cantley (Weill Cornell Medical College) on oncogenic kinases and mechanisms of response to targeted therapies, with a focus on breast cancer. His work has been published in *Nature* and *Science*. He has received the NIH/NCI K08, the Susan G. Komen Career Catalyst Research Award, the ASCO Young Investigator Award, and was named a 2020 AACR NextGen Star. He will be starting his independent laboratory at Columbia University in July 2021.

CURRICULUM VITAE**Neil Vasan**

New York, NY 11101

Email: vasann@mskcc.org

EDUCATIONAL BACKGROUND

M.D./Ph.D. Yale University School of Medicine, New Haven, CT	2005-2013
A.B./A.M., Chemistry (with Honors), Harvard University, Cambridge, MA	2001-2005

PROFESSIONAL POSITIONS AND EMPLOYMENT

Assistant Attending Physician, Breast Medicine Service Memorial Sloan Kettering Cancer Center, New York, NY	2018-present
Instructor, Department of Medicine, Weill Cornell Medical College, New York, NY	2018-present
Chief Fellow, Memorial Sloan Kettering Cancer Center, New York, NY	2016-2017
Fellow in Medical Oncology, Memorial Sloan Kettering Cancer Center, New York, NY	2015-2018
Resident in Internal Medicine, Massachusetts General Hospital, Boston, MA	2014-2015
Intern in Internal Medicine, Massachusetts General Hospital, Boston, MA	2013-2014

RESEARCH EXPERIENCE

Postdoctoral Research Mentors: Dr. Lewis Cantley, Dr. Maurizio Scaltriti, and Dr. José Baselga Weill Cornell Medical Center, Memorial Sloan Kettering Cancer Center Project: Mechanisms of activation and inhibition of PI3K in breast cancer	2016-present
Investigator on 60 IRB protocols (40 open, 20 closed) Memorial Sloan Kettering Cancer Center	2018-present
Dissertation Research with Dr. Karin Reinisch Yale University School of Medicine, Department of Cell Biology Dissertation title: "Structural studies of the GARP tethering complex"	2007-11
Research Assistant with Dr. Matthew Shair Harvard University, Department of Chemistry	2004-05
Research Assistant with Dr. E.J. Corey Harvard University, Department of Chemistry	2003-04
Summer Research Assistant with Dr. Philippe Baran The Scripps Research Institute, La Jolla, CA.	2003
Summer Research Assistant with Dr. Raymond Evers Merck & Co., Inc., Rahway, NJ	2002

FELLOWSHIPS AND GRANTS

NIH/NCI K08 (\$1,217,750 over 5 years)	2020-25
NIH/NCI SPORE in Genomic Instability in Breast Cancer, DRP (\$250,000 over 5 years)	2020-25
Susan G. Komen Career Catalyst Research (CCR) Grant (\$450,000 over 3 years)	2019-22
Innovations in Cancer Informatics Grant (\$200,000 over 2 years)	2018-20
ASCO Young Investigator Award (\$50,000 over 1 year)	2018-19
Society of MSK Research Grant (\$100,000 over 1 year)	2018-19
NIH T32 (CA009207) Investigational Cancer Therapeutics Training Program Grant	2016-18
Society for Translational Oncology Fellows' Forum	2017
AACR Molecular Biology in Clinical Oncology Workshop	2016
NIH F30 (HL097628-01) Predoctoral National Research Service Award (NRSA)	2009-12
NIH Medical Scientist Training Program (MSTP) Fellowship	2006-13

ACADEMIC AND PROFESSIONAL HONORS

AACR NextGen Star	2020
John Mendelsohn Housestaff Teaching Award (MSKCC)	2016

Associate Faculty Member, Faculty of 1000	2010-12
NIH-NHLBI Medical Student Research Fellowship	2006
Merck-Geraldine R. Dodge Foundation Fellowship	2002
Harvard College Scholarship and Dean's List	2001-05
Robert C. Byrd Scholarship	2001-05
National Merit Scholar	2001-02
United States Presidential Scholar (Given to top male high school graduate in WV)	2001
Eagle Scout	2001

PROFESSIONAL ASSOCIATIONS

European Society of Medical Oncology	2019-present
American Association for Cancer Research	2015-present
American Society of Clinical Oncology	2014-present
American Society for Cell Biology	2008-11
American College of Physicians	2005-2013

SERVICE

PI3K Disease Modeling and Drug Targeting Worldwide Zoom Seminar Co-organizer	2020-present
MSKCC Junior Faculty Council member	2019-present
ASCO Membership Advisory Committee Early Career Working Group member	2019-present
ASCO Virtual Mentoring Program	2018-present
ASCO University Review Panel member	2017-2018
AACR Associate Member Council member	2016-2019
ASCO Trainee Council member	2016-2018
Ad-hoc reviewer for <i>Breast Cancer Research, Cancer, Cell Death and Differentiation Hematology/Oncology and Stem Cell Therapy</i>	2018
Moderator for <i>New England Journal of Medicine Resident 360</i>	2016

PEER-REVIEWED PUBLICATIONS

Gorelick A, Sanchez-Rivera F, Cai Y, Bielski C, Biederstedt E, Jonsson P, Richards A, **Vasan N**, Penson A, Friedman N, Ho YJ, Baslan T, Bandlamudi C, Scaltriti M, Schultz N, Lowe S, Reznik E, Taylor B. Phase and context shape the function of composite oncogenic mutations. *Nature* 2020 582:100-103.

Razavi P, Dickler MN, Shah PD, Toy W, Brown DN, Won HH, Li BT, Shen R, **Vasan N**, Modi S, Jhaveri K, Caravella BA, Patil S, Selenica P, Zamora S, Cowan AM, Comen E, Singh A, Covey A, Berger MF, Hudis CA, Norton L, Nagy RJ, Odegaard JI, Lanman RB, Solit DB, Robson ME, Lacouture ME, Brogi E, Reis-Filho JS, Moynahan ME, Scaltriti M, Chandarlapaty S. Alterations in *PTEN* and *ESR1* promote clinical resistance to alpelisib plus aromatase inhibitors. *Nature Cancer* 2020 1:382-393.

Vasan N, Razavi P, Johnson JL, Shao H, Shah H, Antoine A, Ladewig E, Gorelick A, Lin TY, Toska E, Xu G, Kazmi A, Chang MT, Taylor BS, Dickler MN, Jhaveri K, Chandarlapaty S, Rabadan R, Reznik E, Smith ML, Sebra R, Schimmoller F, Wilson TR, Friedman LS, Cantley LC, Scaltriti M*, Baselga J*. Double *PIK3CA* mutations in *cis* increase oncogenicity and sensitivity to PI3K α inhibitors. *Science* 2019 366:714-723.

This work has been featured in multiple publications:

- 1) Perspective by Dr. Alex Toker (*Science* 2019, 366:685-686)
- 2) Online Research Watch in *Cancer Discovery* (DOI: 10.1158/2159-8290.CD-RW2019-172)
- 3) News in Depth in *Cancer Discovery* (DOI: 10.1158/2159-8290.CD-ND2020-013)
- 4) In The Literature in *ESMO Open* (DOI: 10.1136/esmooopen-2020-00680)
- 5) Genomeweb.com (www.genomeweb.com/cancer/double-mutations-pik3ca-gene-increase-patient-sensitivity-targeted-therapies-study-finds#.Xp79WY-z2u5)
- 6) "Your Drug Mileage May Vary: The PIK3CA Double Mutation Story" by Liz Tseng in *Medium* (<https://medium.com/pacbio/your-drug-mileage-may-vary-the-pik3ca-double-mutation-story-83f41f6a4f61>)

Razavi P, Chang MT, Xu G, Bandlamudi C, Ross DS, **Vasan N**, Cai Y, Bielski CM, Donoghue MTA, Jonsson P, Penson A, Shen R, Pareja F, Kundra R, Middha S, Cheng ML, Zehir A, Kandath C, Patel R, Huberman K, Smyth LM, Jhaveri K, Modi S, Traina TA, Dang C, Zhang W, Weigelt B, Li BT, Ladanyi M, Hyman DM, Schultz N, Robson ME, Hudis C, Brogi E, Viale A, Norton L, Dickler MN, Berger MF, Iacobuzio-Donahue CA, Chandarlapaty S,

Scaltriti M, Reis-Filho JS, Solit DB*, Taylor BS*, Baselga J*. The genomic landscape of endocrine resistant advanced breast cancers. *Cancer Cell* 2018 34:427-438.

Vasan N, Yelensky R, Wang K, Moulder S, Dzimitrowicz H, Avritscher R, Wang B, Wu Y, Cronin MT, Palmer G, Symmans WF, Miller VA, Stephens P, Puzstai L. A Targeted Next Generation Sequencing Assay Detects a High Frequency of Therapeutically Targetable Alterations in Primary and Metastatic Breast Cancers: Implications for Clinical Practice. *Oncologist* 2014 19:453-458.

Vasan N, Hutagalung A, Novick P, and Reinisch KM. Structure of a C-terminal fragment of its Vps53 subunit suggests similarity of the Golgi-associated retrograde protein (GARP) complex to a family of tethering complexes. *PNAS* 2010 107:14176-81.

REVIEW ARTICLES & CASE REPORTS

Vasan N, Hyman DM, and Baselga, J. A view on drug resistance in cancer. *Nature* 2019 575:299-309.

Vasan N, Toska E, Scaltriti M. Overview of the relevance of PI3K pathway in HR-positive breast cancer. *Ann Oncol* 2019 30:3-11.

Vasan N, Braghiroli MI, Shoushtari AN, *et al.* An elderly man with remote history of metastatic melanoma now with localized pancreas cancer and new liver masses. *Journal of Gastrointestinal Oncology* 2017 8:596-602.

Vasan N and Dickler MN State-of-the-Art Update: CDK4/6 Inhibitors in ER+ Metastatic Breast Cancer. *AJHO* 2017 13:16-22.

Vasan N, Boyer JL, and Herbst RS. A Ras renaissance: emerging targeted therapies for KRas-mutated non-small cell lung cancer. *Clin Cancer Res* 2014 20:3921-3930.

Vasan N, Saglan O, Killelea BK. Metastatic leiomyosarcoma presenting as bilateral, multifocal breast masses. *BMJ Case Reports* 2012 doi:10.1136/bcr-2012-007188.

BOOK PUBLICATIONS

Vasan N, Carlo M, Dylon A, Postow M. Pocket Oncology, 2nd edition. Lippincott, Williams, & Wilkins, 2018.

Bhushan V, Le T, **Vasan, N**, Tolles J. First Aid for the USMLE Step 1 2010. McGraw-Hill Company, 2010.

Bhushan V, Le T, Grimm L, **Vasan N**. First Aid for the USMLE Step 1 2009. McGraw-Hill Company, 2009.

CONFERENCE PRESENTATIONS

Identifying novel ways to overcome or prevent drug resistance. AACR 2020 Virtual Conference. June 2020. Invited speaker.

Double *PIK3CA* mutations in *cis* enhance PI3K α oncogene activation and sensitivity to PI3K α inhibitors in breast cancer. AACR 2020 Virtual Conference. June 2020. Invited speaker.

Double *PIK3CA* mutations in *cis* enhance PI3K α oncogene activation and sensitivity to PI3K α inhibitors in breast cancer. San Antonio Breast Cancer Symposium 2019. San Antonio, TX. December 12, 2019. Poster presentation.

Double *PIK3CA* mutations in *cis* enhance PI3K α oncogene activation and sensitivity to PI3K α inhibitors in breast cancer. ESMO Breast Cancer 2019. Berlin, Germany. May 2, 2019. Oral presentation.

Double *PIK3CA* mutations in *cis* enhance PI3K oncogene activation and sensitivity to PI3K α inhibitors in breast cancer. AACR Annual Meeting. Atlanta, GA. April 2, 2019. Poster presentation.

Double *PIK3CA* mutations in *cis* enhance PI3K oncogene activation and sensitivity to PI3K α inhibitors in breast cancer. The Tumour Cell: Plasticity, Progression and Therapy. New York, NY. March 5, 2019. Poster presentation.

Compound *PIK3CA* mutations support a mutational dose response model for oncogene activation and response to PI3K inhibitor targeted therapy in breast cancer. AACR Targeting PI3K/mTOR Signaling. Boston, MA. December 1, 2018. Poster presentation.

On the Shoulders of Giants. American Society of Clinical Oncology. Chicago, IL. June 2, 2017. Invited speaker.

PLATO Foundation 5th Annual Fellows Forum in Breast Oncology. Chicago, IL. June 3, 2016. Invited speaker.

Structure of a C-terminal fragment of its Vps53 subunit suggests similarity of the GARP complex to a family of tethering complexes. American Society for Cell Biology annual meeting, Philadelphia, PA, 2010. Invited speaker.

Structural studies of the GARP tethering complex. American Society for Biochemistry and Molecular Biology Special Symposium on the Secretory and Endocytic Pathways, Tahoe City, CA, 2010. Poster presentation.

Structural studies of the GARP tethering complex (poster). National MD/PhD Student Conference, Keystone, CO, 2010. Poster presentation.

EDUCATIONAL PRESENTATIONS

Advances in Lobular Breast Cancer. New York Metastatic Breast Cancer Conference, New York, NY. October 5, 2019. Invited speaker.

Advances in Hormone Receptor Positive Breast Cancer. Living Beyond Breast Cancer 2019 Conference on Metastatic Breast Cancer, Philadelphia, PA. April 6, 2019. Invited speaker.

Targeting Cell Cycle Progression: The latest advances on CDK4/6 inhibition in metastatic breast cancer. Peninsula Regional Medical Center, Salisbury, MD. February 2, 2018. Invited speaker.

Targeting Cell Cycle Progression: The latest advances on CDK4/6 inhibition in metastatic breast cancer. Maimonides Cancer Center, Brooklyn, NY. January 17, 2018. Invited speaker.

Targeting Cell Cycle Progression: The latest advances on CDK4/6 inhibition in metastatic breast cancer. John Theurer Cancer Center, Hackensack, NJ. January 11, 2018. Invited speaker.

REFERENCES

Lewis Cantley
Meyer Director of the Sandra and Edward Meyer Cancer Center
Professor of Cancer Biology in Medicine
Weill Cornell Medical College
LCantley@med.cornell.edu

José Baselga
Executive Vice-President, Research and Development Oncology
AstraZeneca
Jose.Baselga@astrazeneca.com

Maurizio Scaltriti
Associate Attending Biologist, Department of Pathology, Human Oncology & Pathogenesis Program
Associate Director of Translational Science, Center for Molecular Based Therapy
Memorial Sloan Kettering Cancer Center
scaltrim@mskcc.org

Luis Diaz
Head of the Division of Solid Tumor Oncology
Grayer Family Chair
Memorial Sloan Kettering Cancer Center
LDiaz@mskcc.org

Mark Robson
Chief, Breast Medicine Service
Memorial Sloan Kettering Cancer Center
robsonm@mskcc.org



**Walter M. Stadler, MD, FACP
Fred C. Buffett Professor
Depts of Medicine & Surgery
Dean for Clinical Research
Deputy Director, Comprehensive Cancer Center**

I am a clinical trialist who has focused on the development of novel therapies and biomarkers in genitourinary cancers. In this context, I have contributed to the development of gemcitabine in bladder cancer, VEGFR and PD1 checkpoint inhibitors in renal cancer, and various hormonal and other targeted therapies in prostate cancer. I have also explored novel trial designs for growth inhibitory agents, considered the necessary clinical characteristics of both molecular and imaging predictive biomarkers, co-authored consensus statements on prostate cancer clinical trial methodology, and am currently addressing novel pharmacologic approaches to mitigating the cost of care and patient financial toxicity. In my current role as Dean for Clinical Research at the University of Chicago, I am responsible for expanding our clinical trials and clinical research activities throughout the enterprise across departments and centers as well as across our clinical network. Working with the Dean for Translational Research/CTSA Director, I seek to enhance infrastructure and support, including informatics support, to provide the tools for faculty to conduct innovative clinical and translational research activities. In this role I have responsibility for all clinical research regulatory, finance and policy for the institution and have a reporting relationship to University level research management.

CURRICULUM VITAE

WALTER M. STADLER, M.D., FACP

Work: University of Chicago Medical Center
Department of Hematology/Oncology
5841 S. Maryland Ave, MC2115
Chicago, IL 60637-1470
Voice: (773)702-4150
Fax: (773)834-0188
e-mail: wstadler@medicine.bsd.uchicago.edu

Academic Appointments:

1994-1995: Instructor, University of Chicago, Section Hematology/Oncology
1995-1996: Clinical Instructor, University of Chicago, Section Hematology/Oncology
1996-1997: Research Associate (Assistant Professor), University of Chicago, Section Hematology/Oncology
1997-2001: Assistant Professor, University of Chicago, Depts. of Medicine and Surgery, Sections of Hematology/Oncology and Urology
2001-2006: Associate Professor, University of Chicago, Depts. of Medicine and Surgery, Sections of Hematology/Oncology and Urology
2006- : Professor, University of Chicago, Depts. Of Medicine and Surgery, Sections of Hematology/Oncology and Urology
2007- : Fred C. Buffett Professor of Medicine
2007-2014: Associate Dean for Clinical Research
8/13-4/19: Section Chief, Section Hematology/Oncology
8/13- : Deputy Director, University of Chicago Comprehensive Cancer Center
4/19 -: Dean for Clinical Research

Academic Training

Undergraduate Education/Experience:

1980-1984: University of Illinois at Champaign/Urbana, B.S. in Chemistry, Summa Cum Laude with highest distinction in curriculum
1983-1984: General Chemistry Teaching Assistant, University of Illinois
1983-1984: Biochemistry Research Assistant, University of Illinois

Medical Education/Experience:

1984-1988: Yale University School of Medicine, M.D.
1984-1986: Undergraduate Tutor, Yale University
1987-1988: Leader of Student Plan Primary Care Clinics, Yale University

1985-1988: Medical Student Advisor
1987: General Medicine Student Rotation, Alaska Indian National Health Service, Bethel, Alaska
1989-1991: Resident Staff Member, AIDS Clinic, Michael Reese Hospital and Medical Center

Post Graduate Education:

1988-1991: Michael Reese Hospital and Medical Center, Resident in Internal Medicine
1990: Instructor, Physical Diagnosis Course for oral surgeons
1990-1991: Volunteer Instructor, Physical Diagnosis Course for 2nd year medical students
1991-1994: University of Chicago, Fellow in Hematology/Oncology

Licensure & Certification:

ABIM Board Certification #135876
Board Certified, General Internal Medicine, 9/91, 5/02, 10/12
Board Certified, Oncology, 11/93, 5/02, 11/13
IL State License: 036-081259

Professional Societies:

American College of Physicians, 1989-
American Association for the Advancement of Science, 1991-
American Federation for Medical Research, 1992-
American Association for Cancer Research, 1991-
American Society of Clinical Oncology, 1995-
American Urological Association, Affiliate Member, 1996-
The Society of Urologic Oncology, Affiliate Member, 1996-
Society for Basic Urologic Research, 1999-2009
Central Society for Clinical Research, 2001-2014
Clinical Research Forum, 2008-2014
Society for Clinical and Translational Science, 2010-

Honors and Awards:

1984: Bronze Tablet, University of Illinois' highest academic award
Phi Beta Kappa Nominee
Nine separate merit scholarships or awards as undergraduate
1991: Alfred Pick Award for Academic Excellence, Michael Reese
1992-1994: Walgreen Fellow
1994: ASCO Young Investigator Award
1996: Cancer Research Foundation, Young Investigator Award
1999: Kidney Cancer Association, Stulberg Clinical Investigator Award
2000: Univ of Chicago Cancer Research Foundation Auxiliary Board annual award
2002: Fellow, American College of Physicians-American Society of Internal Medicine
2005- : Best Doctors in America
2007- : Castle Connolly Medical Ltd, America's Top Doctor's for Cancer

Clinical Service

I am a clinical oncologist focused on the care of patients with genitourinary malignancies. I staff 2 half day clinics per week and attend on the general inpatient oncology services for 6 weeks/year

Scholarship:

Peer-reviewed publications in the primary literature, exclusive of abstracts:

1. **Stadler WM**, Richards JM, Vogelzang NJ. Serum IL-6 level in metastatic renal cell cancer: Correlation with survival but not an independent prognostic indicator. *J Natl Cancer Inst* 84:1835-1836, 1992
2. **Stadler WM**, Vogelzang NJ, Vokes EE, Charette J, Whitman G. Continuous infusion FUDR with leucovorin and high dose interferon: A phase II study in metastatic renal cell cancer. *Cancer Chemother Pharmacol*, 31:213-216, 1992
3. **Stadler WM**, Sherman J, Bohlander SK, Roulston D, Rukstalis D, Dreyling M, Olopade OI. Homozygous deletions within chromosomal bands 9p21-22 in bladder cancer. *Cancer Res* 54:2060-2063, 1994
4. Yeager T*, **Stadler WM***, Belair C, Olopade OI, Puthenveetil J, Olopade OI, Reznikoff C. Increased p16 levels correlate with pRb alterations in human urothelial cells. *Cancer Res* 55:493-497, 1995(*These authors contributed equally to the manuscript)
5. Olopade OI, Pomykala HF, Hagos F, Sveen L, Espinosa R, Dreyling M, Gursky S, **Stadler WM**, LeBeau MM, Bohlander SK. Construction of a 2.8 megabase YAC contig and cloning of the Methylthioadenosine phosphorylase (MTAP) gene from the tumor suppressor locus on 9p21. *Proc Natl Acad Sci USA*, 92:6489-6493, 1995
6. **Stadler WM**, Rybak ME, Vogelzang NJ. A phase II study of subcutaneous human recombinant IL-4 in metastatic renal cell cancer. Evidence of biologic and clinical activity. *Cancer*, 76:1629-1633, 1995
7. **Stadler WM**, Olopade OI. The 9p21 region in bladder cancer cell lines: Large homozygous deletions inactivate the *CDKN2*, *CDKN2B*, and *MTAP* genes *Urol Res* 24:239-244, 1996
8. Shulman KL, **Stadler WM**, Vogelzang NJ. High dose continuous intravenous infusion interleukin-2 (IL-2) therapy for metastatic renal cell carcinoma, the University of Chicago experience. *Urology* 47:194-197, 1996
9. Soloway MS, Briggman JV, Carpinito GA, Chodak GW, Church PA, Lamm DL, Lange PH, Messing EM, Pasciak RM, Reservitz GB, Rukstalis DB, Sarosdy MF, **Stadler WM**, Thiel RP Hayden CL. Use of a new tumor marker, urinary NMP22, in the detection of occult or rapidly recurring transitional cell carcinoma of the urinary tract following surgical treatment. *J. Urol* 156:363-367, 1996
10. Carpinito, GA, **Stadler WM**, Briggman JV, Chodak GW, Church PA, Lamm DL, Lange PH, Messing EM, Pasciak RM, Reservitz GB, Ross RN, Rukstalis DB, Sarosdy MF, Soloway MS Thiel RP, Vogelzang NJ, Hayden CL. Urinary nuclear matrix protein (NMP22) as a marker for transitional cell carcinoma of the urinary tract. *J Urol* 156:1280-1285, 1996
11. Reznikoff CA, Yeager T, Belair CD, Savelieva E, Puthenveetil JA, **Stadler WM**. Elevated p16 in senescent human uroepithelial cells is retained upon E7 but not E6 induced immortalization. *Cancer Res.* 56:2886-2890, 1996

12. Reeder JE, Morreale JF, O'Connell MJ, **Stadler WM**, Olopade OI, Messing EM, Wheelless LL. Loss of the *CDKN2/p16* locus detected in bladder irrigation specimens by fluorescence in situ hybridization. *J Urol* 158:1717-1721, 1997
13. **Stadler WM**, Kuzel T, Roth B, Raghavan D, Dorr FA. A phase II study of single agent gemcitabine in previously untreated patients with metastatic urothelial cancer. *J Clin Oncol.* 15:3394-3398, 1997
14. Yeager TR, DeVries S, Jarrard DF, Kao C, Nakada SY, Moon TD, Bruskewitz R, **Stadler WM**, Meisner LF, Gilchrist KW, Newton MA, Waldman FM, Reznikoff CA. Overcoming cellular senescence in human cancer pathogenesis. *Genes Devel* 12: 163-174, 1998
15. Rini BI, **Stadler WM**, Spielberger R, Vogelzang NJ. Granulocyte-Macrophage Colony-Stimulating Factor (GM-CSF) in Metastatic Renal Cell Cancer: A Phase II Trial. *Cancer* 82:1352-8, 1998
16. Kirsh EJ, Baunoch DA, **Stadler WM**. Expression of bcl-2 and bcl-X in bladder cancer. *J Urol.* 159:1348-1353, 1998
17. Vogelzang NJ, Mani S, Schilsky RL, Ansari RH, Taber D, Rhinehart SN, Garcia JC, Meyer SC, Mick R, Schumm LP, Brockstein BE, **Stadler WM**, Ratain MJ, Vokes EE. Phase II and pharmacodynamic studies of pyrazine diazohydroxide (NSC 361456) in advanced renal and colorectal cancer. *Clin Cancer Res* 4:929-934, 1998
18. **Stadler WM**, Kuzel T, Dumas M, Vogelzang NJ. A multi-center phase II trial of interleukin-2, interferon- α , and 13-cis-retinoic acid in patients with metastatic renal cell carcinoma. *J Clin Oncol.* 16:1820-1825, 1998
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Abstracts/Scientific Presentations

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Pamphlets, Brochures, Misc Publications, and Lay Press

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4. **Stadler WM**. Interview for: "In Focus: Renal Cell Carcinoma, Angiogenesis Inhibition in Non-Clear Cell Renal Cancer." *Clinical Advances in Hematology Oncology*, 6:507-509, 2008

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7. **Stadler WM**. How Do I TreatA Patient with Newly Diagnosed Metastatic Renal Cancer. Oncology Times v32, issue 24 (Dec 25, 2010)
8. **Stadler WM**. Key GU Takeaways, ASCO 2011. Oncology Times v33, issue 16 (Aug, 2011)
9. **Stadler, WM**. Key GU Takeaways, ASCO 2012. Oncology Times (online first posted 6/11/12)

FUNDING

Pending

Organization	Title	Role	Dates
2 P50 CA180995-06A1	SPORE in Prostate Cancer	Project Co-PI	pending

Current

Organization	Title	Role	Dates
NIH 2-P30-CA14599-35	Cancer Center Support Grant	Deputy Director	4/23/13-3/31/23
2 K12 CA139160-11	Developing an Oncology Workforce for the 21st Century	Co-PI	8/1/15 – 7/30/25
NIH P50CA180995	SPORE in Prostate Cancer	Project Leader & Admin Core Co-director	8/18/15 – 7/31/20

Past

Organization	Title	Role	Dates
American Cancer Soc. (Res. Training Award)	The 9p21-22 Tumor Suppressor Gene in Bladder Cancer	Principal Invest.	7/1/94 - 6/30/97
American Society of Clinical Oncology (Young Invest. Award)	The Role of the 9p21-22 Tumor Suppressor Gene in Bladder Cancer	Principal Investigator	7/1/94 – 6/30/95
Kettering Family Found.	NA	Principal Invest.	7/1/95 - 6/30/96
Cancer Res. Found.	The role of p16 in Human Urothelial Cell Senescence and Bladder Cancer Oncogenesis	Principal Invest.	7/1/96 - 6/30/97

Univ. Chicago Cancer Res. Center	Chemoprevention Pilot Project	Principal Invest.	7/1/97 - 6/30/98
American Cancer Soc. (RPG-97-171-01-CNE)	The CDKN2 Gene in Urothelial Senescence and Oncogenesis	Principal Invest.	7/1/97 - 6/30/00
NIH UO1 (U0-CA63187-04S2)	Phase II Trials of New Anti-Cancer Agents	Co-Invest.	7/21/99 – 3/31/00
NIH R21 (CA78883-01)	Biomarkers for Bladder Cancer Chemoprevention Trials	Principal Invest.	7/1/98 - 6/30/01
Mesothelioma Applied Research Foundation	Biologic markers for VEGF inhibitors in mesothelioma therapy	Co-Investigator	12/15/00 – 12/31/01
American Cancer Soc. (RPG-99-068-01-CSM)	Identification of Prostate Cancer Metastasis-Suppressor Genes on Human Chromosome 12	Co-Invest.	1/1/99 - 12/31/02
Kidney Cancer Assoc. (Stulberg Award)	Synergistic Activity of Gemcitabine and 5FU in Renal Cancer: A Translational Investigation	Principal Invest.	7/1/99 – 7/16/02
NIH P30 CA14599-28	Cancer Center Support Grant	Program Co-leader	4/1/02 – 9/1/03
DOD Prostate Program	Neoadjuvant Antiangiogenesis Therapy for Prostate Cancer	Co-Investigator	4/01/02 – 11/30/04
DOD Prostate Program	Planning grant for Clinical Trials; Androgen Replacement in Hormone Refractor Prostate Cancer	Principal Investig.	8/01/04 – 7/30/05
NIH RO1 1R01CA089569	Prostate Cancer Metastatic Colonization: Role of MKK4	Co-Invest.	4/1/01 – 3/31/06
University of Chicago Cancer Research Center Pilot Project	Experimental validation of a novel method for estimating the contrast agent arterial input function in dynamic contrast enhanced MRI studies	Principal Invest.	7/1/05 – 6/30/06
NIH RO1 (CA71921-02)	MVAC in Organ-Confined Bladder Cancer Based on p53 Status	Co-Invest.	7/01/01- 3/31/07
NIH R21 CA108184-01A2	Dynamic-contrast enhanced MRI as a BAY 43-9006 marker	Principal Invest.	7/1/05 – 6/30/07

NIH P30 CA14599-28	Cancer Center Support Grant	Clinical Trials Review Committee Chair	9/1/03 – 3/31/08
American Cancer Society – IL Division	Decision Making in Older Men Starting Androgen Ablation for Prostate Cancer	Co-Invest	9/1/08 – 8/31/10
P50 CA090386	Prostate Cancer SPORE	Co-Investigator & Executive Committee member	3/1/09 – 12/31/13
NIH UO1 CA69852-04	Phase I Clinical Trials of Anti-Cancer Agents	Co-Invest.	5/10/95 – 2/28/13
DOD Clinical Consortium PC081013	Clinical Trials Consortium	Principal Invest.	9/1/09 – 8/31/14
DOD W81XWH-13-1-0451	The Genomic Evolution of Prostate Cancer	Mentor (Vanderweele)	10/1/13 – 7/1/16 (mentee transferred)
NIH contract (N01-CM-62201)	Early Therapeutics Development with Phase II Emphasis	Principal Invest.	2/1/01 – 9/22/16
NIH 1 UM1 CA186705-01	Experimental Therapeutics: Clinical Trials Network with Phase I Emphasis	Co-Invest	3/26/14 – 2/29/17
Movember-PCF	Prostate Cancer Challenge Award	Co-Invest	8/1/14 – 8/1/16
DOD/ARDA – MSKCC W81XWH-15-2-0018	Prostate Cancer Research Program Clinical Consortium Award	Principal Invest.	6/5/15 – 6/14/18
Prostate Cancer Foundation 16CHAL12	Combinatorial Immunotherapy Strategies to Reverse Immunosuppression within PTEN-deficient Advanced Prostate Cancers	Co-Invest	12/31/16-12/31/18
Prostate Cancer Foundation 16CHAS04	Use of selective GR antagonists in castration-resistant prostate cancer	Co-Invest	12/31/16-12/31/18

Invited Speaking

Regional Tumor Board, Grand Rounds, and CME lectures (genitourinary oncology):

12/7/95: Univ. of Chicago CME course “Genitourinary Oncology: A Multidisciplinary Approach”

2/8/96: St. Catherine Hospital (also coordinated presentations by various UC cancer

physicians for St. Catherine's cancer CME program)
2/19/96: Elkhardt General Hospital
3/15/96: Rush Copley Health Center
5/23/96: Bronson Medical Center, Kalamazoo, MI
5/24/96: Merrillville Cancer Associates
10/22/96: Holy Cross Hospital
11/13/96: South Suburban Hospital
11/23/96: Univ. of Chicago CME course "New Developments in the Management of Solid

Tumors”

2/10/97: Christ Hospital
2/20/97: Lagrange Hospital
12/3/97: Little Company of Mary Hospital
3/6/98: Holy Cross Hospital
8/26/98: St. Joseph Hospital, South Bend, IN
12/2/98: Chicago Urologic Society (letter attached)
2/28/99: St. Joseph Hospital, South Bend, IN
4/27/99: Holy Cross Hospital
7/2/99: Provena St. Marys, Kankakee, IL
7/799: Munster Community Hospital, Munster, IN
10/20/99: Rockford Oncology Assoc., Rockford, IL
11/30/99: Oncology/Hematology Assoc. of Northern Illinois, Grayslake, IL
12/7/99: Holy Cross Hospital
7/12/00: South Suburban Hospital
4/10/01: Preceptorship, Abbott Laboratories staff
7/12/01: Oncology/Hematology Associates of Central Illinois, Decatur, IL
7/26/01: University of Illinois Section of Hematology/Oncology, Chicago, IL
10/16/01: Preceptorship, Abbott Laboratories staff
11/21/01: Ingall’s Hospital Richard Desser Memorial Program, Harvey, IL
1/29/02: Preceptorship, Abbott Laboratories staff
3/7/02: Cook County Hospital, Chicago, IL
4/2/02: MacNeal Hospital, Berwyn, IL
7/23/02: Preceptorship, Abbott Laboratories staff
9/17/02: Preceptorship, Roche staff
10/22/02: Northwest Oncology/Hematology, Arlington Hts, IL
5/14/03: Little Company of Mary, Evergreen Park, IL
10/17/03: Central Illinois Oncology, Peoria, IL
10/29/03: Lutheran General Hospital, Park Ridge, IL
3/23/04: Holy Cross Hospital Tumor Board
4/1/04: Prostate Cancer Outreach Event, Univ. of Chicago Gleacher Center
11/22/04: South Suburban Hospital, Hazel Crest, IL
3/9/05: Renal Cancer Update, Chicago, IL
4/23/05: University of Chicago Prostate Cancer Symposium, Gleacher Center, Chicago, IL
12/14/05: Renal Cancer Update, Evanston, IL
1/31/06: Munster Community Hospital, Munster, IN
2/16/06: Community practitioners, Tinley Park, IL
4/1/06: Renal Cancer Challenging Case Conference, Chicago, IL
5/10/06: Community practitioners, Rosemont, IL
6/21/06: Community practitioners, Chicago, IL
12/6/06: Chicago Urologic Association, Chicago, IL
4/25/07: Univ. Of Ill/Chicago Urology Department, Chicago, IL
6/30/07: KCA patient conference, Chicago, IL
7/26/07: Community practitioners, Joliet, IL
7/28/07: ASO ASCO highlights, Chicago, IL
2/9/08: Community practitioners, Decatur, IL
4/4/08: Phase II network conference, Chicago, IL
6/7/08: KCA patient conference, Chicago, IL
8/23/08: Index Emerging Therapies in Solid Tumor Oncology, Chicago, IL
9/6/08: Second Annual Perspectives in Urologic Oncology, Chicago, IL
11/5/08: Chicago Urologic Society, Chicago, IL

2/3/10: Chicago Urologic Society, Chicago, IL
4/22/10: Lutheran General Hospital, Park Ridge, IL
8/10/10: Glenbrook Hospital UsToo Chapter, Glenview, IL
10/22/10: Illinois Cancer Care, Peoria, IL
11/20/10: Lombard UsToo Chapter, Lombard, IL
12/2/10: NorthShore University Health System, Kellogg Cancer Center, Evanston, IL
4/19/11: Michiana Hematology/Oncology, Granger, IN
4/20/11: Chicago Urologic Society, Chicago, IL
9/27/11: Northern Indiana CME Foundation
10/29/11: University of Chicago Update in GU Oncology, Chicago, IL
11/9/11: Chicago Urologic Society, Chicago, IL
1/25/12: Visiting Professor, Rush University, Chicago, IL
3/10/12: Trends Hematology/Oncology, Lutheran General Hospital, Park Ridge, IL
7/12/12: Prime Oncology, ASCO Ancillary Conference, Chicago, IL
11/8/12: Gilda's Club, Chicago, IL
10/7/13: UsToo, Glenbrook Hospital, Glenview, IL
11/6/13: Chicago Urologic, Chicago, IL
11/16/13: UsToo, Lombard, IL
1/16/14: Gilda's Club, Chicago, IL
2/13/14: Lutheran General Hospital, Park Ridge, IL
4/30/14: Specialty Review in Urology, Naperville, IL
7/10/14: ASCO Update, Northwestern, Chicago, IL
7/10/15: ASCO Update, Northwestern, Chicago, IL
8/30/15: Society for Immunotherapy of Cancer, Symposium, Chicago, IL
11/16/15: Northwestern University Medical Center, Medical Grand Rounds, Chicago, IL
6/13/17: Medicine Grand Rounds, University of Chicago, Chicago, IL

Invited National Tumor Board, Grand Rounds, and CME lectures (genitourinary oncology)

10/15/96: Upstate New York Cancer Research Foundation, Rochester, NY
5/22/97: Gemcitabine in cancer, Washington DC
6/6/97: Association of Northern California Oncologists, Sacramento, CA
11/12/97: Chemotherapy Foundation Symposium XV, Mt. Sinai, New York, NY
2/11/98: New York University, New York, NY
3/12/98: Univ. of Pittsburgh, Pittsburgh, PA
5/1/98: Providence Hospital, Detroit, MI
9/26/98: Sacred Heart Cancer and Research Center, Spokane, WA
10/19/98: Optimizing Solid Tumor Therapy: Innovation, Advance, and Insights, Melville, NY
11/14/98: American Society Clinical Oncology Fall CME Conference, Chicago, IL
11/26/98: Community Hospital of Los Gatos, San Jose, CA
2/19/99: MetroHealth, Cleveland, OH
3/24/99: Cleveland Clinic, Cleveland, OH
4/22/99: John Muir Medical Center & Pacific Hematology/Oncology & Sisters of Mercy Hospital,

Sacramento, San Francisco, & Redding, CA
4/29/99: Spectrum Health Center, Grand Rapids, MI
5/28/99: Mt. Sinai Hospital, Miami, FL
6/2/99: Exploring Options for Advanced Lung and Bladder Cancer, St. Louis, MO
8/5/99: St. Joseph Mercy, Ann Arbor, MI
10/7/99: US Oncology, Scottsdale, AZ
10/9/99: South Carolina Oncology Association, Myrtle Beach, SC
12/3/99: Scripps Clinic, La Jolla, CA
2/2/00: Marion VA Hospital, Marion, IL
3/17/00: Solid tumor update 2000, Vail, CO
5/4/00: Beth Israel & St. Vincents, New York, NY
5/24/00: American Society of Clinical Oncology Annual Meeting, Expert commentary on oral research presentations for bladder cancer.
5/26/00: Oakwood Hospital, Dearborne, MI
6/15/00: Good Samaritan Hospital, West Islip, NY
6/28/00: Univ. of Oklahoma, Oklahoma City, OK
10/13/00: Schering sponsored conference call update on metastatic renal cell carcinoma
11/9/00: Cancer and Leukemia Group B continuing education series, renal cell carcinoma
11/13/00: Upper Valley Medical Center, Troy, OH
1/17/01: Muskegon Oncology Chapter (ONS), Muskegon, MI
2/21/01: University of Texas, Galveston, TX
2/21/01: Memorial Hermann Healthcare System, Houston, TX
2/22/01: MDAnderson Cancer Center, Houston TX
3/16/01: Challenging Cases in Patient Management, Atlanta, GE
5/23/01: El Paso Oncology Consultants, El Paso, TX
5/24/01: Del Sol Medical Center, El Paso, TX
5/26/01: Brooke Army Medical Center, San Antonio, TX
5/26/01: Univ. Texas, Health Science Center, San Antonio, TX
6/2/01: Society of Urologic Oncology, Annual Meeting, Anaheim, CA
6/4/01: Univ. of Southern California, Los Angeles, CA
6/29/01: Lilly Global Oncology Young Investigator Meeting, Chair, Bladder Cancer Session
9/17/01: Milwaukee oncologists
1/28/02: Fairview Hospital, Cleveland, OH
1/28/02: Cleveland Community Oncologists, Cleveland, OH
6/19/02: Kidney Cancer Association Annual Patient Meeting
9/14/02: ASCO Update, Dallas, TX
9/28/02: Kaiser Permanente Annual Oncology Conference, Berkley, CA
10/30/02: Missouri Baptist Medical Center, St. Louis, MO
12/5/02: Private oncologist group, Minneapolis, MN
1/15/03: GU Opinion Leader's Summit, St. Thomas, UVI
5/6/03: Baylor College of Medicine, Department of Urology, Houston TX
6/1/03: American Society of Clinical Oncology Annual Meeting, Expert commentary on poster

presentations for renal cancer

6/13/03: Post-ASCO Update, Pittsburgh, PA

7/15/03: Decatur Memorial Hospital, Decatur, IL

7/18/03: Chair, annual Kidney Cancer Association Patient Conference, Chicago, IL

8/15/03: University of Iowa, Iowa City, IO

10/18/03: Annual Fall Oncology Conference, Hilton Head, SC

11/13/03: Introduction to Oncologic Product Development, Phase II trials, New York, NY

2/25/04: Third International Symposium on Genitourinary Cancers, Santa Barbara, CA

3/19/04: Innovations and Challenges in Renal Cell Cancer, Cambridge, MA

6/1/04: ASCO annual meeting, Education session on renal cell cancer, Orlando, LA

6/24/04: Genitourinary Malignancies, Translating Laboratory Discoveries Into Clinical Realities. Organizing Committee, Renal Cancer Session Moderator, and Speaker, Univ. Iowa, Iowa City, IA

8/13/04: First International Congress on Kidney/Bladder Cancers, Organizing committee and speaker, Orlando, FL

8/19/04: St Louis, MO community oncologists, Clayton, MO

9/3/04: Fourth International Congress on Antibodies in Cancer, Colorado Springs, CO

9/17/04: Kidney Cancer: New Therapeutic Options, Washington DC

10/14/04: Wassau Hospital and Marshfield Clinic, Wassau, WI

10/21/04: St Louis, MO community oncologists, Clayton, MO

10/25/04: Ohio State University, visiting professor, Columbus, OH

11/13/04: International Kidney Cancer Symposium, Chicago, IL

1/26/05: Fourth International Symposium on Genitourinary Cancers (Organizing Committee), Los Angeles CA

3/18/05: Univ. of Nebraska Medical Grand Rounds, Omaha, NE

4/17/05: AACR annual meeting: Educational session on bladder cancer, Anaheim, CA

5/17/05: Post ASCO Symposium: Emerging Strategies for the Treatment of Advanced Kidney Cancer, Orlando, FL

5/24/05: AUA plenary session: Renal Cancer Highlights, San Antonio, TX

6/24/05: Emerging Trends in Oncology: A post-ASCO update, Seattle, WA

7/15/05: Second International Congress on Kidney/Bladder Cancers, Organizing committee and speaker, Orlando, FL

9/16/05: Kidney Cancer: New Therapeutic Options, Washington DC

10/22/05: Kidney Cancer Assoc. International Conference, Chicago, IL

11/13/05: International Oncology Network, Dallas, TX

11/20/05: CALGB meeting, GU committee, update on RCC, Amelia Island, FL

1/27/06: 5th Multidisciplinary Symposium on Genitourinary Cancers (Organizing Committee),

Dana Point, CA

2/9/06: Marshfield Clinic, Marshfield, WI

2/13/06: Private practitioners, Minneapolis, MN

3/15/06: University of Miami Sylvester Cancer Center, Miami, FL

3/20/06: University of Minnesota, Minneapolis, MN

4/11/06: Memorial Medical Center, Springfield, IL

5/16/06: Ohio State University, Columbus, OH

5/24/06: Walter Reed Army Hospital, Bethesda, MD

6/6/06: ASCO, Industry Sponsored Satellite Symposium on RCC, Atlanta, GA

7/29/06: Post-ASCO update, Chicago, IL

8/5/06: 3rd International Kidney/Bladder Cancer Congress, Orlando, FL (organizing committee)

9/23/06: Kidney Cancer Association International Symposium, Chicago, IL

10/7/06: AUA Conference on Kidney/Bladder Cancers, Miami, FL

10/9/06: Private practitioners, Virginia Beach, VA

11/4/06: NMCR Challenges in Genitourinary Cancer, San Francisco, CA

11/18/06: Current Trends in Genitourinary Cancer, New York, NY

12/1/06: Radiology Society of North America, Chicago, IL

1/27/07: Paul Peters Urology Symposium, Univ Texas Southwestern, Dallas, TX

2/11/07: NCI/AACI IRAT Network meeting, Phoenix, AZ

6/2/07: ASCO – Poster discussion leader, RCC, Chicago, IL

10/6/07: Update on GU Malignancies, Boston, MA

10/12/07 : KCA International Symposium, Chicago, IL

11/16/07: Visiting Professor, Cleveland Clinic, Cleveland, OH

11/27/07: RSNA/NCI Interventional Oncology Series, RSNA, Chicago, IL

11/29/07: Private practitioners, Minneapolis, MN

12/1/07: Society of Urologic Oncology, Bethesda, MD

1/11/08: Visiting Professor, Roswell Park University

2/16/08: ASCO GU, Bladder Cancer Trial Design, San Francisco, CA

4/30/08: Yale Annual Prostate and Urologic Malignancies Conference, New Haven, CT

5/5/08: Infusion Nurses Society, Phoenix, AZ

5/17/08: NOCR continuing medical education, Miami, FL

5/31/08: ASCO National Meeting, Beyond Response Rate: Novel Clinical Endpoints and Trial Designs, Chicago, IL

6/2/08: ASCO National Meeting, Rational Choices for RCC Therapy, Education session chair

10/3/08: Research-to-Practice: Renal Cancer Experts Roundtable, Miami, FL

10/10/08: Oncology Symposium, St. Joseph, MI

12/2/08: RSNA, Interventional Radiology Course, Renal Cancer

1/22/09: Karmanos Cancer Institute Grand Rounds, Detroit, MI

2/27/09: Masters Class, Renal Cancer, Orlando, FL

4/20/09: AACR National Meeting, New Concepts in Organ Site Research, Renal Cancer: Co-

7/17/09: opting the Hypoxia Pathway for Oncogenesis and Taking It Back for Therapeutics, Chair
 PER Congress on Genitourinary Malignancies, Renal Cancer Speaker, Washington DC
 9/2/09: Dana Farber Cancer Center, GU Cancer Grand Rounds
 5/20/10: CancerCare teleconference – Progress in the Treatment of Renal Cell Cancer.
 8/12/10: Dana Farber Kidney Cancer SPORE invited speaker
 8/13/10: Annual Innovations and Challenges in Renal Cancer, Cambridge, MA
 11/29/10: Radiologic Society of North America (RSNA), Focus on Imaging Biomarkers
 2/11/11: NOCR – Renal cancer therapy update, Las Vegas, NV
 3/15/11: Univ of North Carolina, Chapel Hill, NC
 6/6/11: ASCO National Meeting, Poster Discussion, Renal Cancer Therapeutics
 7/16/11: ImDex ASCO Update Meeting, Houston, TX
 7/25/11: Forsyth Regional Cancer Center, Winston-Salem, NC
 8/30/11: University of Vermont Cancer Center, Burlington, VT
 10/15/11: International Kidney Cancer Association Meeting, Chicago, IL
 10/30/11: The Angiogenesis Foundation, Boston, MA
 11/8/11: City of Hope Hematology/Oncology Grand Rounds, Duarte, CA
 11/28/11: Radiologic Society of North America (RSNA), Chicago, IL
 3/16/12: Oncology Grand Rounds, Cleveland Clinic, Cleveland, OH
 7/21/12: Highlights in Oncology from ASCO, San Francisco, CA
 10/11/12: ASCO/EORT/NCI Molecular Markers Meeting, Scientific Program Chair
 4/17/13: BCAN webinar
 6/17/13: Research to Practice Audio and Video Roundtable on Renal Cell Cancer
 2/15/14: Oncology Meetings Innovations, Dallas, TX
 2/20/14: Imedex NOCR, Las Vegas, NV
 10/4/14: Regional Prostate Cancer Summit, Dava Oncology, NY, NY
 2/27/15: Urothelial Cancer Tumor Board, ASCO GU, Orlando, FL
 2/27/15: Clinical Challenges in Castrate Resistant Prostate Cancer, Orlando, FL
 3/14/15: NOCR, Las Vegas, NV
 3/21/15: Southeast Wisconsin Cancer Conference, Milwaukee, WI
 6/2/15: Discussant, ASCO annual meeting, GU Oral Session, Chicago, IL
 9/18/15: Comprehensive Board Review in Hematology & Medical Oncology (Bladder Cancer),
 MD Anderson, Houston, TX
 11/6/15: Kidney Cancer Association, Miami, FL
 11/21/15: Research to Practice, Santa Monica, CA
 6/6/16: ASCO annual meeting, Poster Discussant, Chicago, IL
 6/18/16: ASCO update, Nebraska Oncology Society, Omaha, NE
 7/23/16: ASCO Highlights, Aurora Health, Milwaukee, WI
 9/9/16: West Hawaii Cancer Symposiu, Kona, Hawaii
 9/19/16: MDAnderson Oncology Board Review Course
 10/21/16: Genitourinary Cancer Summit, New York, NY
 10/15/16: Kidney Cancer Association Annual Symposium, Miami, FL
 10/21/16: GU Cancer Summit, NY NY (Chair)
 11/5/16: Kidney Cancer Association Annual Symposium, Miami, FL
 2/17/17: Immune Checkpoint Inhibitors in Advanced Bladder Cancer, Orlando, FL
 11/3/17: Correlatives Associated with Bevacizumab/Atezolizumab, Kidney Cancer Association

International Kidney Cancer Symposium, Miami, FL
 6/1/18 OncLive, Renal Cancer Therapy (online); Chicago. IL
 7/11/18 AACI meeting, Clinical Research Infrastructure and the CCSG, Chicago, IL
 7/28/18 ASCO/AACR Clinical Trials Course, Vail, CO
 8/11/18 Aurora Healthcare ASCO Highlights, Milwaukee, WI
 9/7/18 West Hawaii Cancer Symposium, Kona, HI
 9/20/18 OncLive GU Oncology, Chicago, IL
 5/4/19 SBUR/SUO symposium at AUA, Therapeutic Advances in Multimodality Therapy in Urologic Malignancies, Chicago, IL
 5/5/19 AUA 18th International Prostate Forum, Chicago, IL
 6/22/19 Best of ASCO, Omaha, NE
 7/31/19 ASCO/AACR Clinical Trials Course, Vail, CO
 8/22/19 University of Kentucky Oncology Grand Rounds
 8/24/19 Best of ASCO, Milwaukee, WI
 10/26/19: Aurora Health System Annual Cancer Symposium, Green Bay, WI
 1/24/20: Univ of North Carolina, Chapel Hill, NC
 9/10/20: DAVA Oncology, Recent Advances in Urothelial Cancers (Virtual)

Invited International lectures (genitourinary oncology)

2/28/97: Update on gemcitabine in cancer, St. Thomas, Virgin Islands
 9/3/97: Lilly-International advisory meeting, Stockholme, Sweden
 7/10/99: International Baltic Uro-oncologic Symposium, Kiel, Germany
 10/15/99: Mexican National Cancer Institute, Puerto Vallarta, Mexico
 2/21/00: Live satellite TV broadcast to South American Oncologists
 3/21/00: Deutscher Krebskongress (Annual meeting of German Oncology Society), Berlin, Germany
 4/18/02: Targeted Therapies in the Treatment of Genitourinary Cancers, Barcelona, Spain
 10/31/03: Heinrich Warner Foundation, Hamburg, Germany
 6/11/05: Best of ASCO in Japan, Tokyo, Japan
 8/20/05: 15th Bayer Symposium on Advances in Urology, Fukuoka, Japan
 9/24/05: Deutsche Gesellschaft für Urologie (German Urology Society)
 3/24/06: Deutscher Krebskongress (Annual meeting of German Oncology Society), Berlin, Germany
 6/14/06: European Spring Oncology Meeting, Marbella, Spain
 10/4/06: Princess Margaret Hospital, New Developments in Cancer Management, Toronto,

Canada
 10/18/06: Japan Society of Clinical Oncology
 12/14/06: Clinical Oncologists, Madrid (and other Spanish cities via satellite)
 4/14/07: Japan Urologic Association
 5/5/07: Tawain Joint Cancer Conference
 9/11/08: World Molecular Imaging Conference, Nice, France
 11/20/08: Tom Baker Cancer Center, Calgary, Canada
 11/21/08: British Columbia Cancer Agency Community Oncologists, Vancouver, Canada
 5/14/09: V Curso Interdisciplinario de Oncologia: Tumores Urologicos, Oviedo, Spain
 4/22/11: Oncology Congress Brno, Brno, Czech Republic
 9/22/12: International Bladder Cancer Network, Neijmegan, Netherlands
 11/8/13: ASCO/EORTC/NCI Molecular Markers Meeting, Scientific Program Committee
 9/23/15: GU Malignancies Summit, Banf, Canada
 10/21/17: International Bladder Cancer Network, Lisbon, Portugal
 12/8/17: International Conference on Onconephrology, Naple, Italy
 10/11/18: International Bladder Cancer Network, Rotterdam, Netherlands
 11/1/18: OMI GU Conference, Banff, Canada
 12/14/18: International Conference on Onconephrology, Milan, Italy
 10/12/19: DAVA GU Conference, Banff, Canada

Editorial Activities:

Ad hoc Reviewer: Cancer, Clinical Cancer Research, Journal of Clinical Oncology, Cancer Investigation, Investigational New Drugs, British Journal Cancer, JAMA, PNAS, J Clin Oncol
 Guest Editor: Seminars in Oncology “Bladder Cancer”, V23, No 5, Oct. 1996
 Reviewer: AHFS Drug Information, 1998
 Reviewer: ABIM certifying examination questions in oncology, 1998, 1999
 Reviewer: AUA annual meeting abstracts: 2007
 Reviewer: AUA bladder cancer guidelines: 2007
 Guest Editor: Kidney Cancer Journal, Vol 6, No1, 2008
 Editorial Boards:
 Nexcura: 2000-2005
 Journal of Clinical Oncology: 2001-2004
 Clinical Genitourinary Cancer: 2001- 2009
 UpToDate Oncology Peer Review Board: 2003-
 Medscape, Genitourinary Oncology “Journal Scan Author”: 2004-2006
 British Journal of Urology: 2006-2010
 Kidney Cancer Journal: 2006-2010
 The Oncology Report: 2010-2012
 Oncology Real Time: 2011-2013
 Cancer (GU section editor): 2011 –
 Bladder Cancer: 2014 -

Teaching Activities (in addition to housestaff, fellow education)

Undergraduate teaching

1996-2005: Laboratory Assistant, Clinical Pathophysiology, 2nd yr medical students:
 1997-1999: Guest lecturer, Frontiers in Cancer Research: Malignant Progression and its Treatment, Graduate seminar

Graduate, Post-graduate teaching

1996-2002 Laboratory Instructor, Hematology section, Clinical Pathophysiology (2nd yr medical students)

1997-2001 Cancer Biology Course #315 “Frontiers in Cancer Research” (Cancer Biology Graduate Students) One lecture each year on translational research

1/00 Cancer Biology Committee Retreat, Development of Targeted Therapeutics

11/5/10 Cancer Biology Personalized Genomics Course: Lecture on Biomarkers

2007-2014: Essentials of Patient Oriented Research, Annual lecture on principal investigator responsibilities

2012 Clinical Protocol Development Workshop (CCTS 44100), One of 3 preceptors for workshop designed for fellows/junior faculty to write a protocol

7/31 – ASCO/AACR Annual Clinical Trials Workshop Preceptor

Hematology/Oncology Fellow Lecture Series

Annual educational lectures on prostate, bladder, testes and renal cancer

Urology Resident Lecture Series

Annual lecture on renal cancer, testes cancer

Multidisciplinary Uro-oncology Conference

Weekly Conference of genitourinary cancer cases

Laboratory trainees:

1995-96: Evan Goldfischer, MD

1996-97: Edward Kirsch, MD

1996-97: Mark Chien (Undergraduate Research Thesis)

1997: Donald VanderGriend (Summer Undergraduate Student)

1997-1998: Craig Turner, MD (AFUD Scholar Award)

1998: Julia Sorisho (High school summer intern – 1st prize city-wide science fair)

Janet Roddick (Howard Hughes Medical Institute summer research fellowship)

1999: Jason Balthius (Summer Undergraduate Student)

1999-2004: Thelma Tenent (PhD thesis committee)

1999-2005: Donald VanderGriend (PhD graduate trainee)

2001: Hyo Lee (Summer Undergraduate Student)

2001: Russ Wright (Summer Undergraduate Student)

2011-2014: Steve Kregal (PhD thesis committee)

2012-2013: Erin Mowers (PhD thesis committee)

2018-2019: Matt Trendowski (PhD thesis committee)

Advanced GU clinical research fellows:

1998-2000: Christopher Ryan, MD

1999-2001: Brian Rini, MD

2000-2001: Apurva Desai, MD

2000-2003: Christopher George, MD

2001-2003: Nancy Davis, MD

2002-2004: Andrew Artz, MD

2002-2004: Mebea Aklilu, MD

2003-2004: Amy Peterson, MD

2003-2004: Stacy Gray, MD

2003-2005: Supriya Gupta, MD

2004-2006: Ou (James) Jin, MD, Ph.D.

2004-2005: Blase Polite, MD

2005-2007: Katherine Bylow, MD
2005-2007: Olwen Hahn, MD
2006-2007: David Knight, MD, Ph.D.
2007-2009: Russell Szmulewitz, MD
2007-2010: Peter O'Donnell, MD
2008-2009: Elizabeth Chung, MD
2009-2012: James Chen, MD
2010-2013: David Vanderweele, MD, PhD
2010-2011: Tobi Nwizu, MD
2011-2013: Dan Geynisman, MD
2012-2015: Saleha Sajid, MD
2015-2019: Randy Sweis, MD
2015-2018: Jamie Brewer, MD
2018- 2020: Brian Heiss, MD
2020- : Priyanka Chablani, MD

Junior faculty GU research mentees:

2000-2003: Christopher Ryan, MD
2001-2006: Apurva Desai, MD
2004-2006: Amy Peterson, MD
2005-2011: Edwin Posadas, MD
2006-2010: William Dale, MD, PhD (Geriatrics)
2007-2013: Olwen Hahn, MD
2007-2009: Stacy Lindau, MD (Gynecology)
2008-2010: Aytakin Oto, MD (Radiology)
2009-2018: Russell Szmulewitz, MD
2010-2018: Peter O'Donnell, MD
2013-2015: David Vanderweele, MD, PhD
2016- : Akash Patnaik, MD, PhD
2019: Arpita Desai
2019- : Randy Sweiss, MD
2020- : Brian Heiss, MD

Service

Internal Committees/Programs/Centers:

1985-1987: Thesis Committee
1985-1988: Basic Science Curriculum Committee
1988: Task Force for Curriculum Evaluation
1996: Ad hoc Committee on Oncology Outpatient Clinic, Chair
1998-1999: Univ. of Chicago, Div. Biological Sciences, Ad hoc committee on Core Facilities
1999-2001: Univ. of Chicago, Dept. of Medicine, Assist. Professor Advisory Committee
1995- : Univ. Chicago Comprehensive Cancer Center (UCCCC)
1995-2001: Molecular Genetics Program Member
1995-2003: Prostate/GU Cancer Program Member
1998-2007: Clinical Trials Review Committee Member
1999-2003: Vice-Chair
2003-2007: Chair
2000- : Clinical and Experimental Therapeutics Program Member (Renamed:
Pharmacogenomics and Experimental Therapeutics in 2011)
2009- 2019: Program co-leader
2000-2003: Assoc. Director, GU Cancer Program

2001- : Executive Committee Member
 2003-2007: Clinical Research Oversight Committee
 2009- : Clinical Research Oversight Committee
2013 – : Deputy Director
 2004-2010: MRI Core Facility Faculty Oversight Committee
 2006-2013: Pharmacology Core Facility Oversight Committee, chair
 2010-2015: Epidemiologic Research Core Facility Oversight Committee
 2010-2014: Cancer Advisory Committee
 2000-2001: Hospital “Triad” Committee member (Patient care committee formed to coordinate activities of Hematology/Oncology and inpatient hospital oncology floor staffs)
 2000: Ad hoc Search Committee for new Chair of Radiology
 2000-2003: Section Hematology/Oncology Data Manager Committee
 2000-: Section Hematology/Oncology Fellowship Selection Committee
 2000-2008: Faculty Fund Raising Working Group
 2006-2008: Chair
 2001-: Hematology/Oncology Fellowship Training Grant, Executive Committee
 2002-2004: Institutional Biosafety Committee
 2002-2004: Tissue Collection and Utilization Steering Committee
 2002 -: Committee on Cancer Biology
 2005: Ad hoc committee on reorganization of inpatient services
 2005-2007: Department of Medicine Clinical Research Advisory committee
 2006-2019: Biostatistics Facility Faculty Advisory Committee
 2007-2010: University Council of the Senate (Faculty Advisory Committee to University President)
 2007-2013: Biomedical Imaging Institute Steering Committee
 2007-2013: Clinical Research Policy Committee, Chair
 2008-2011: BSD Committee on Appointments and Promotions
 2009-2010: University of Chicago/NorthShore University Research Subcommittee
 2009-2011: Cancer Clinical Care Operations Committee
 2010-2013: Human Immunology Monitoring Facility Faculty Advisory Committee
 2010-2017: Institute for Translational Medicine, Executive Committee
 2011-2016: Human Biofluids Collection Facility Faculty Advisory Committee
 2011: Ad Hoc Committee on Evaluation of the Imaging Research Institute
 2011-2012: New Hospital Pavilion, Transformational Leadership Committee
 2011-2012: AURA (University Research Informatics System) Steering Committee
 2011-2014: Tissue Allocation and Distribution Committee
 2011-2014: Electronic Health Records (EHR) Advisory Committee
 2011-2012: LCME Task Force
 2012-2016: Research Informatics Governance Committee
 2013- 2018: Molecular and Clinical Pathology Laboratory Clinical Working Group
 2013-2014: Post-acute care advisory committee
 2013 - : Divisional Compliance Committee
 2014: Ad hoc advisory committee on cGMP Facility
 2014- 2019: Divisional Cancer Strategy Committee, Steering Committee member
 2015-2017: MRI Research Center Faculty Advisory Committee

External Boards/Committees

1995: Review panel member (molecular biology): United States Army Breast Cancer Research Program
 1999- : Kidney Cancer Association
 1999- : Medical Advisory Board
 2006-2010: Board of Directors

1998- : Cancer and Leukemia Group B (CALGB) – Changed name to ALLIANCE 2012
 1998- : GU Core Committee Member
 2000-2010: CALGB GU Core, Renal Cell Cancer Cadre Leader
 2007-2010: Genitourinary Cancer Intergroup, Renal Cancer Subcommittee
 2000-2004: American Cancer Society, Illinois Division, Research Advisory Committee
 2001: NCI Kidney/Bladder Cancer Progress Review Group, Subcommittee Chair
 2003: NCI GU/Prostate SPORE Application Review Panel
 2003: Case Western Reserve/Ireland Cancer Center, external advisor, annual faculty retreat
 2003-2006: Data safety monitoring committee, Wyeth CCI-779 phase III trial
 2004-2006: American College of Radiology Imaging Network, GU committee
 2004: International Consensus Committee on Neoadjuvant and Adjuvant Therapy of Bladder Cancer
 2004-2008: External Advisory Board, MD Anderson Bladder Cancer SPORE
 2005- : NCI Special Emphasis Panel, Loan Repayment Program reviewer
 2005-2007: American Joint Committee on Cancer (AJCC) Genitourinary Cancer Task Force
 2005- : Bladder Cancer Advocacy Network Medical Advisory Board
 2006-2008: American Society of Clinical Oncology – Scientific Program Committee,
 2006-2008: GU Track Member
 2007-2008: GU Track Leader
 2006-2008: Data safety monitoring committee, Novartis RAD001 RCC trial
 2008-2010: Chair, data safety monitoring committee, Wyeth temsirolimus vs sorafenib RCC trial
 2008-2012: RSNA Quantitative Imaging Biomarker Alliance
 2008: Ad Hoc advisory committee, Huntsman Cancer Institute
 2008: Ad Hoc external review committee member: Dana Farber Cancer Institute
 2008: Ad Hoc reviewer, NCI P01 Discovery and Development Panel
 2008-2013: Oncology Drug Advisory Committee to FDA
 2008-2017: Chair, External Advisory Board: Northwestern Hematology Oncology T32 Training Grant
 2009-2016: NCI/CTEP Investigational Drug Steering Committee
 2006-2015: NCI/CTEP Biomarkers Task Force
 2008-2015: Co-chairman
 2009-2012: Review Panel, Cancer Prevention and Research Institute of Texas (CPRIT)
 2010-2012: Aveo phase III renal cancer trial Data Safety Monitoring Committee
 2010: Ad Hoc reviewer, Cancer Center Review Panel (Subpart A)
 2010: ASCO-NCI-EORTC Molecular Biomarkers Meeting, (Markers in Cancer)
 2010-2011: Scientific Program Committee Member
 2012: Scientific Program Committee Chair
 2011: Kansas “Rising Star” review committee
 2012: Ad Hoc reviewer, Cancer Center Review Panel (Subpart A)
 2012-2017: NCI Board of Scientific Councilors (Clinical Sciences and Epidemiology)
 2012: Ad Hoc reviewer, NIH Developmental Therapeutics Study Section
 2014-2016: American Joint Commission on Cancer (AJCC), 8th edition, Kidney/Urinary Tract expert panel, Chair
 2014- : Chair, Data Safety Monitoring Committee Sotio Phase 3 prostate cancer clinical trial
 2014: Ad Hoc reviewer, NIH Special Emphasis Panel, ZCA1 RPRB-7 (O3) NCI
 2014: International Society of Urological Pathology, Prostate Cancer Grading Meeting
 2014- : Review Panel, Cancer Prevention and Research Institute of Texas (CPRIT)
 2014: Review Panel, DOD Genetic and Cancer Research – Kidney Cancer
 2014: Prostate Cancer Foundation, Challenge Awards Program Review Panel
 2016: NIH ad hoc SPORE Review Panel, Co-Chair

2016 - Data Safety Monitoring Committee, Eisai, Phase 3 trial of levantinib/everolimus or levantinib/pembrolizumab vs sunitinib in renal cancer

2016 - Data Safety Monitoring Committee, Astra-Zeneca, Phase 3 Durvalumab vs Durvalumab + Tremelimumab vs standard chemo in first line metastatic urothelial cancer

2016 - : Data Safety Monitoring Committee, Bayer, Phase 3 Study of ODM-201vs Placebo plus Standard Androgen Deprivation and Docetaxel in Prostate Cancer

2017: NIH ad hoc SPORE Review Panel, Co-Chair

2017 - 2019: Data Safety Monitoring Committee, Astra-Zenece, Phase 3 Durvalumab vs Durvalumab/Tremelimumab vs Standard Chemotherapy in Bladder Cancer

2018 - : Data Safety Monitoring Committee, Astra-Zeneca, Phase 3 Durvalumab + BCG versus BCG for non-muscle invasive bladder cancer

2018 - : Data Safety Monitoring Committee, Astra-Zeneca, Phase 3 Durvalumab +/- Tremelimumab +/- Standard Chemotherapy

2018 - : Data Safety Monitoring Committee, Astra-Zeneca, Phase 3 Gemcitabine/Cisplatin w/wo Durvalumab for Neoadjuvant therapy of Bladder Cancer

2019 - : Data Safety Monitoring Committees, Merck prostate cancer pembrolizumab program (3 separate phase 3 trials)

2019: Chair, DOD Kidney Cancer Clinical Trials Consortium Review Panel

2019: ASCO Conquer Cancer Foundation Young Investigator Award Review Panel

2020: DOD Kidney Cancer Concept Award Review Panel