

Weill Cornell Medical College, Cornell University

Faculty Curriculum Vitae Template

Name: Massimo Cristofanilli, M.D., F.A.C.P.

Signature:



Date of Preparation: 1/20/2022

A. PERSONAL DATA

Office address: Weill-Cornell Medicine
Larson Building, LH-204
420 E 70th St.
New York, NY 10021

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Home address: 1330 First Ave
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New Yor, NY 10021

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Email address - Work: Mac9795@med.cornell.edu

Email address - Personal:
Is your eligibility to work in the U.S. based on an employment visa?: NO
If yes, please provide Visa type (Example: J-1, H-1B, E-3, TN, etc.): N/A

B. EDUCATION (*Bachelor's and higher*)

MD, Medicine University La Sapienza, Rome, Italy 11/1979 – 11/1986

C. POSTDOCTORAL TRAINING (*Include residency/fellowships*)

Fellowship, Medical Oncology, Oncology Certification with Honors	University La Sapienza, Rome, Italy	12/1986–11/1990
Fellowship, Clinical Pathology (not completed)	University La Sapienza, Rome, Italy	1/1991–1/1993
Internship, Internal Medicine	Cabrini Medical Center, New York, NY, A. Taranta, MD	7/1993–6/1994
Resident (PGY-2), Internal Medicine	Cabrini Medical Center, New York, NY, W. Talavera, MD	7/1994–6/1995
Elective Rotation, Medical Oncology	Memorial Sloan Kettering Cancer Center, New York, NY, A. Surbone, MD	1/1995–6/1995
Chief Resident, Internal Medicine	Cabrini Medical Center, New York, NY, W. Talavera, MD	7/1995–6/1996

Elective Rotation, Hematology	Memorial Sloan Kettering Cancer Center, New York, NY, L. Gee, MD	5/1996
Fellowship, Medical Oncology	The University of Texas M. D. Anderson Cancer Center, Houston, TX, Richard Pazdur, MD	7/1996–6/1998
Methods in Clinical Research 4th Annual Workshop	The University of Texas M. D. Anderson Cancer Center, Vail, CO	7/1999–8/1999
Program for Chiefs of Clinical Services	Harvard School of Public Health, Boston, MA	1/2012

D. PROFESSIONAL POSITIONS & EMPLOYMENT

Academic Appointments (*Teaching and research, i.e. Instructor, Assistant Professor, etc.*)

Professor of Medicine	Weill-Cornell Medicine, NYP	01/1022-present
Chief of Breast Medical Oncology	Sandra Meyer Cancer Center, NY	
Associate Director of Precision Oncology		
Professor of Medicine		08/2015 – 1/4/2022
Associate Director of Translational Research and Precision Medicine	Northwestern University, Robert H Lurie Comprehensive Cancer Center, Chicago, IL	
Professor of Medical Oncology	Thomas Jefferson University/Kimmel Cancer Center, Philadelphia, PA	1/2013-8/2015
Deputy Director of Translational Research		
Director of the Breast Center and Medical Oncology Program		
Professor of Medical Oncology Chairman, Department of Medical Oncology	Fox Chase Cancer center, Philadelphia PA	1/2010-122012
Leader, Breast Service Line		
Associate Cancer Center Director for Clinical Research		
Co-Leader, CCSG Women's Cancer Program		
Director of Translational Science, Cancer Genome Institute		
Associate Professor of Medicine Assistant Professor	Department breast Medical Oncology, The University of Texas, M D Anderson Cancer Center	9/2003-12/2009
Founder and Director Morgan Welch IBC Research program and clinic	Division of Cancer Medicine, The University of Texas M. D. Anderson Cancer Center, Houston, TX	

Hospital Appointments (*Clinical, i.e., Assistant Attending, Attending, etc.*)

Professor of Medicine Department of Medicine, Division of Hematology & Oncology	Weill-Cornell Medicine, NYP Sandra Meyer Cancer Center, NY	1/10/22-present
Professor of Medicine, Department of Medicine, Division of Hematology & Oncology	Northwestern University, Robert H Lurie Comprehensive Cancer Center, Chicago, IL	08/2015 – 1/4/2022

Other Professional Positions & Employment (*Industry, private practice, etc.*)

Scientific Director, EIPM	Weill-Cornell Medicine, NYP Sandra Meyer Cancer Center, NY	1/10/2022-Present 08/2015 – 1/4/2022
Director of the OncoSET Precision Medicine Program		
Leader of the Breast Disease Team	Northwestern University, Robert H Lurie Comprehensive Cancer Center, Chicago, IL	

E. LICENSURE, BOARD CERTIFICATION

Licensure: *Every physician appointed to the NYP Hospital staff, except interns, and aliens in the US via non-immigrant visas, must have a New York State license or a temporary certificate in lieu of the license.*

State	Number	Date of issue (mm/dd/yyyy)	Date of last registration (mm/dd/yyyy) – (mm/dd/yyyy)
Illinois	336.100606		07/31/2023
DEA number: (optional)	BC5620352	07/20/2021	7/20/2021 – 08/31/2024
NPI number: (optional)	1891880563		

If no license:

- (1) Do you have a temporary certificate? NO
- (2) Have you passed the examination for foreign medical school graduates? YES

Board Certification

ABIM	171015
	American Board of Internal Medicine, Certification, 1996–2006

ABIM-Medical Oncology,
1999

Recertification Medical
Oncology, 2010-2022

F. INSTITUTIONAL/HOSPITAL AFFILIATION

Primary Hospital Affiliation: New York Presbyterian

G. EMPLOYMENT STATUS

Name of Current Employer(s): WCM, NYP
Current Employment Status: Other salaried

If not currently employed by Weill Cornell Medicine, do you anticipate being employed by WCM? Yes

H. HONORS, AWARDS

<i>Name of award</i>	<i>Organization</i>	<i>Date awarded (yyyy)</i>
Clinical Appreciation Certificate for significant clinical skills course	New York Medical College	1996
Clinical Fellow Research Award	The University of Texas M. D. Anderson Cancer Center	1998
Fellow	American College of Physician (FACP)	2003
Outstanding Educator	The University of Texas M. D. Anderson Cancer Center	2003
“Cavaliere del Lavoro” (Knight of the Italian Republic) for outstanding scientific contribution	Italian Republic	2006
Distinguished Alumnus Award	The University of Texas M. D. Anderson Cancer Center	2008
Best Doctor	US News & World Report	2009
Humanitarian Award Finalist	ASCO	2011
Best Doctor	Philadelphia Magazine	2012
Lifetime Achievement Award for Ethics and Creativity in Medical Research	Giovan Giacomo Giordano NIAF	2012
Scientific Research Award	American Cancer Society, Southeast Region	2012

3rd Annual Jamie Brooke Lieberman Remembrance Award	Susan G. Komen Philadelphia Affiliate	2015
Impact Award	IBC Foundation	2016
Breast Cancer Ambassador Award	Morgan Welch Inflammatory Breast Cancer Foundation	2017
Best Breast Cancer Scientific Paper 2016	BJ Club	2017

I. PROFESSIONAL ORGANIZATIONS AND SOCIETY MEMBERSHIPS
(Please include medical and scientific societies.)

<i>Organization</i>	<i>Date (yyyy-yyyy)</i>
Italian Association of Medical Oncology, Italy	1987–present
Italian Society of Immunology, Oncologic Embriology, Italy	1987–1993
Italian Society of Palliative Care, Italy	1990–1993
European Association of Cancer Research (EACR), United Kingdom	1998–present
International Society of Preventative Oncology, United Kingdom	1998–2002
American Association for Cancer Research (AACR), PA	1999–present
American Society of Clinical Oncology (ASCO), VA	2000–present
American Society of Surgical Oncology (ASSOG) Group, TX	2000–present
European Society Medical Oncology (ESMO), Switzerland	2000–present
European Society of Breast Imaging, Austria	2000–present
Southwest Oncology Group (SWOG), MI	2000–2010
American Society of Gene Therapy, WI	2003–2009
American Society of Breast Disease	2005–present
Eastern Cancer Cooperative Group (ECOG)- Breast Committee	2010-present
The Biomarkers Consortium	2009-present
Foundation for the National Institutes of Health (NIH)	
AAAS member	2012-2019
ASCO Biomarkers Expert Panel-Member	2012-2013
American Council of Science and Health-Advisory Board	3/17-Present
International Society of Liquid Biopsy- Chair Nominating Committee	4/17-Present

J. PERCENT EFFORT AND INSTITUTIONAL RESPONSIBILITIES

(When not yet at WCM, report activities at current site; when already at WCM, report only WCM activities.)

Current Site Activity <i>(if not WCM)</i>	Percent Effort (%)	Does the activity involve Weill Cornell students/research trainees? (No)
Teaching	20	
Clinical	35	
Administrative	20	
Research	25	
Total	100%	
Weill Cornell Activity <i>(Current or Anticipated)</i>	Percent Effort (%)	Does the activity involve Weill Cornell students/research trainees? (Yes)
Teaching	10	
Clinical	40	
Administrative	15	

Research 35
Total 100%

K. EDUCATIONAL CONTRIBUTIONS

*Please include title/audience/dates as applicable for each prompt below. Please list only teaching activities at WCM, any of its affiliates, your currently employed institution and previously employed institutions here. If your area of excellence is Educational Leadership, you **must** instead complete the Educator Portfolio. Then, refer to your report here as an attachment (e.g. see attached), and attach it to the CV.*

Didactic teaching (lectures, seminars, tutorials,)

Clinical teaching *I spent 4 half day sessions in the breast clinic with medical oncology fellows attending 2 sessions/month. I serve as the inpatient covering attending for the oncology service for 4 weeks/year. Inpatient team includes 2 junior resident and a second-year supported by a medical oncology fellows. The teaching in the clinic consist of reviewing management guidelines for breast cancer along with review of individual case managements. Incorporation of precision oncology in the real-world with description of technical differences among various tests.*

Inpatient teaching include medical management of treatment side effects, emergencies and, principles of palliative care and endo of life.

Administrative teaching; Developed courses and seminars primarily in the area of precision oncology and breast cancer management. I serve as President of the ISLB and IBC-IC with responsibility to organize annual meetings and webinars.

The University of Texas M. D. Anderson Cancer Center, Conference on Tumor Markers: Discovery to Practice, Santa Barbara, CA, Chair, 3/2003

5th International Conference on Minimal Residual Disease, San Francisco, CA, Co-Chairman, 9/2005

The University of Texas M. D. Anderson Cancer Center, Tumor Markers for Personalized Medicine: The New Frontier, Symposium, Kona, HI, Chair, 3/2006

NIH, Tumor Dormancy Workshop: Tumor Cell Dormancy Think Tank Challenges and Research Opportunities, Bethesda, MD, Chair, 6/2006

The University of Texas M. D. Anderson Cancer Center, First International Inflammatory Breast Cancer Conference, Houston, TX, Chair, 12/2008

UT Health Science Center at San Antonio School of Educational Programs, CTCRC-AACR San Antonio Breast Cancer Symposium, San Antonio, TX, Chair, 12/2008

AIM Group, 1st International Meeting on New Drugs in Breast Cancer, Rome, Italy, Chair, 4/2009

University of Athens, 7th International Congress on Minimal Residual Cancer – Scientific Committee Member, Session III: CTCs and DTCs as tumor biomarkers, Athens, Greece, Chair, 9/2009

The University of Texas M. D. Anderson Cancer Center, Founder of the IBC World Alliance Meeting, San Antonio, TX, Chair, 12/2009

2nd International Conference on IBC- Scientific Committee, Marseille, 10/2010

3rd International Conference on IBC, co-Chair, Philadelphia, 12/2012

Kimmel Cancer Center Breast Symposium, March 2014: Chairman and Founder.

Co-Chair- 5st International Conference on IBC, Boston, 7/16

Co-Chair- 1st OncoSET Precision Medicine Conference, 4/17
Co-Chair- 2nd OncoSET Precision Medicine Conference 5/18
Co-Chair- 6th International Conference on IBC, Madrid, Spain, 9/18
Co-Chair- 3rd OncoSET Precision Medicine Conference, Chicago, April 2019
Co-Chair of the 1st North Africa IBC meeting, Tunis, September 2019
Co-Chair- 2nd ISLB meeting 2020 Virtual meeting
Co-Chair- 4th OncoSET Precision Medicine Conference (Virtual), March 9th, 2021
Scientific committee. 5th ACTC conference, Kalamata (Greece), September 2021
Scientific committee. 3rd ISLB conference virtual meeting, October 2021

Continuing education and professional education as teacher

Participated as invited speaker at many events (CME) on the topics of breast cancer management, novel drugs for metastatic HR+ disease, CTCs and liquid biopsy and IBC. Some presentations summarized in other section of the CV

Community education or patient outreach (*medical journalism and media presentations such as television and radio appearances that educate the public about medicine, health or biomedical sciences*)

L. CLINICAL PRACTICE, INNOVATION, and LEADERSHIP

Clinical Practice

09/2015-12/2021: Northwestern Medicine. Medical oncology inpatient service: 4 weeks. Breast clinic for 3 sessions/week
01/2013-08/2015- Thomas Jefferson University. Medical oncology inpatient service: 4 weeks. Breast clinic for 4 sessions/week
01/2010-12/2012: Fox Chase Cancer Center (Chairman medical oncology). 4 sessions/week of breast clinic. No inpatient service
7/98-12/2009: UT-MDACC, Houston TX. Breast medical oncology. 3 full days of clinic (6 sessions/week). Four weeks inpatient service

Clinical Innovations

NU 2021: *Landscape of circulating tumour DNA in metastatic breast cancer. EBioMedicine. 2020 Aug;58:102914; Longitudinal Dynamics of Circulating Tumor Cells and Circulating Tumor DNA for Treatment Monitoring in Metastatic Breast Cancer. JCO Precis Oncol. 2021 Jun 8;5:943-952; The Use of Serial Circulating Tumor DNA to Detect Resistance Alterations in Progressive Metastatic Breast Cancer. Clin Cancer Res. 2021 Mar 1;27(5):1361-1370. Cell-free DNA comparative analysis of the genomic landscape of first-line hormone receptor-positive metastatic breast cancer from the US and China. Breast Cancer Res Treat. 2021 Nov;190(2):213-226.* Dr. Cristofanilli establishes a clinical/translational precision oncology program to establish guidelines for the use of NGS (tissue and blood) in advanced cancer and to demonstrate the clinical value. He leads a team of multispecialty investigators that publish a series of papers demonstrating the value of longitudinal monitoring in MBC. These evidences contribute to change clinical practice at NMH health system.

TJU. 06/2015. *Palbociclib in Hormone-Receptor–Positive Advanced Breast Cancer, N Engl J Med 2015; 373:209-219.* Dr. Cristofanilli served as senior member of the study Steering Committee that designed the study that demonstrated the significant benefit of palbociclib in combination with fulvestrant over single agent in patients that had failed prior therapies. A final PFS analysis along with biomarkers evaluation was published in the *Lancet Oncology* with Dr. Cristofanilli as first author (2016 Apr;17(4):425-439). Furthermore, Dr. Cristofanilli presented the overall survival data at ESMO 2018 (oral presentation) with concomitant publication *N Engl J Med (2018; 379:1926-1936)*. Palbociclib is the first CDK4/6 inhibitor to receive FDA approval for the management of patients with HR+ MBC in combination with AI or fulvestrant and included in the NCCN guidelines

UT-MDACC. 08/2004: *Circulating Tumor Cells, Disease Progression, and Survival in Metastatic Breast Cancer, N Engl J Med 2004; 351:781-791.* Participated in the design of the study, serves as lead investigator and he was the first author of the manuscript (> 4500 citations). The paper demonstrated for the first time the use of a blood-based diagnostic for prognosis in advanced breast cancer. The technology was FDA-cleared for such indication and became a clinical test. Subsequently, it was also approved for use in advanced prostate and colon cancer. Most recently Dr. Cristofanilli lead a team of investigators to demonstrate that CTCs can be used to stratify stage IV breast cancer with significant impact on management and drug development in the disease (*Crit Rev Oncol Hematol. 2019 Feb;134:39-45*). CTCs detection was recently recognized as a major cancer diagnostic breakthrough and the beginning of the era of liquid biopsy in solid tumors. Dr. Cristofanilli later was among the funders of the international society of liquid biopsy (ISLB) and served as president of the society.

Clinical Leadership

M. RESEARCH

Research Activities:

- 1. CTCs and Liquid Biopsy.** I was among the first to hypothesize that patients clinical outcome and response to treatment can be monitor in real-time by using sensitive blood tests similar to hematological malignancies. I collaborated in the design and led the pivotal trial demonstrating the prognostic value of circulating tumor cells (CTCs) enumeration. That study resulted in the FDA approval of the Cell Search™ technology in metastatic breast cancer and subsequently prostate and colon cancers. More recently, I contributed to the understanding of molecular heterogeneity at mRNA and genomic level in CTCs and cell-free tumor DNA.
- 2. Leader in Inflammatory Breast Cancer (IBC) Clinical and Translational Research.**
In 2006 I started the first multidisciplinary Clinic and Research program focused on inflammatory Breast Cancer (IBC). This was an example of team science applied to the evaluation and treatment of this aggressive form of breast cancer. We designed IBC-directed clinical trials (the first group to test lapatinib in IBC). I led a multi-PI Promise grant from American Airlines and the Susan Komen Foundation (\$7.5M) resulting in a number of discoveries (ALK overexpression in IBC, HDACs inhibitors targeted of E-cadherin) and clinical trials. Founder and President of the International IBC Consortium.
- 3. Leader in Drug Development in Breast Cancer.** I designed and led the prospective study demonstrating the benefit of gefitinib (Iressa™) in first-line treatment of ER+ MBC and the value of lapatinib (Tykerb™) in HER2+ metastatic IBC. I was a Senior member of the Steering Committee and US principal investigator of a large, prospective Phase 3 trial (PALOMA 3) leading to the FDA-approval of palbociclib in HR+ MBC in combination with fulvestrant.
- 4. Leader in molecular diagnostics and Precision Oncology.**
I was among the first medical oncologists to test the use next-generation sequencing (NGS) and transcriptome analysis in patients with advanced breast cancer. We were among the early investigators describing *ESR1* mutations in patients with endocrine-refractory disease.

PROTOCOLS

Principal Investigator, Multimodality approach in the treatment of inflammatory breast carcinoma (IBC), DM98-087, 1999–2000, \$180,000 (\$180,000/year), Bristol Myers Squibb

Principal Investigator, Phase II study of RFS 2000 (9-Nitro-Camptothecin) in recurrent metastatic breast cancer, DM99-235, 1999–2005, \$172,000 (\$34,400/year), SuperGen, Inc.

Principal Investigator, Isolation and enumeration of malignant cells from the peripheral blood of patients with advanced breast cancer, ID99-391, 2001–2003, \$374,940 (\$187,470/year), Immunicon

Principal Investigator (Investigator-initiated), Phase II single arm, single institution clinical trial of Docetaxel and Doxorubicin in combination with local administration of AD5CMV-p53 (RPR/INGN 201) in locally advanced breast cancer, ID00-008, 2001–2005, \$540,000 (\$180,000/year), Introgen Therapeutics, Inc.

Principal Investigator (Investigator-initiated), Phase II trial of PS-341 in metastatic breast cancer, ID00-308, 2002–2003, \$25,000 (\$25,000/year), NCI/CTEP, Translational Research Fund (TRF)

Principal Investigator, Tc99-EC-Annexin-V for imaging of apoptosis: A bio-distribution study in primary breast cancer, ID-02-732, 2002–2003, \$130,865 (\$130,865/year), CellPoint, LCC

Principal Investigator (Investigator-initiated), Phase II trial of STI571 in metastatic breast cancer, ID01-691, 2003–2004, \$75,000 (\$75,000/year), NCI/CTEP, Translational Research Fund (TRF)

Principal Investigator, International stage IV stratification study (ISSS): Prospective validation trial of circulating tumor cells (CTCs) as prognostic and predictive markers in women with metastatic breast cancer about to start first-line treatment, 2005-0278, 2004–2005, \$200,000 (\$200,000/year), Veridex, LLC

Principal Investigator (Investigator-initiated), Phase II multicenter, double blind, randomized trial comparing anastrozole (ZD1033), ARIMIDEXTM) placebo to the combination Anastrozole ZD1839 (Gefitinib, IressaTM) in postmenopausal patients with estrogen receptor (ER) and/or progesterone receptor (PGR), 2003-0587, 2004–2007, \$308,060 (\$308,060/year), AstraZeneca

Principal Investigator, A multicenter, open label, phase II study to evaluate the efficacy, safety and pharmacodynamics of lapatinib in patients with relapsed or refractory inflammatory breast cancer, 2004-0831, 2005–2008, \$237,556 (\$79,185/year), GlaxoSmithKline

Principal Investigator, A randomized, multicenter, phase III study comparing the combination of Pazopanib and Lapatinib versus Lapatinib monotherapy in patients with ErbB2 overexpressing inflammatory breast cancer, 2007-0448, 2007–2009, GlaxoSmithKline

Principal Investigator (Investigator-initiated), A phase I-II study of R115777 (Tipifarnib, Zarnestra) plus sequential weekly paclitaxel followed by dose-dense doxorubicin and cyclophosphamide in patients with stage IIB-IIIC breast cancer, 2007-0766, 2008–2009, \$52,101 (\$52,101/year), NCI/CTEP

Principal Investigator (Investigator-initiated), A phase II study of neoadjuvant Lapatinib plus chemotherapy (sequential FEC75 and paclitaxel) in women with inflammatory breast cancer whose tumors overexpress ErbB2 (Her2/neu), 2007-0818, 2008–2010, \$497,701 (\$248,850/year)

Principal Investigator, Determination of HER2 tumor status by circulating tumor cell (CTC) analysis, LAB06-0975, 2008–2010, \$39,306 (\$19,653/year), Genentech

Principal Investigator (Investigator-initiated), Prospective trial of circulating tumor cells by a polymerase chain reaction based technique (AdnaGen Breast Test) in women with high-risk locally advanced breast cancer that have completed neoadjuvant and local therapy, LAB08-0159, 2012, Alere

Principal Investigator. A Phase II, Randomised, Double-blind, Placebo-controlled, Multi-centre Study to Assess the Efficacy and Safety of AZD8931 in Combination with Anastrozole, Compared to Anastrozole alone, in Post-menopausal Women with Hormone Receptor-positive, Endocrine Therapy-Naïve, Locally-advanced or Metastatic Breast Cancer (MINT)., 2012-AZ

Principal Investigator. An open label multicenter phase 2 window of opportunity study evaluating ganetespib (STA-9090) monotherapy in women with previously untreated metastatic HER-2 positive or triple negative breast cancer, 2012, Synta

Principal Investigator (Investigator-initiated). A Phase1/2 Study of Romidepsin in Combination with Abraxane in Patients with HER-2 neg, Metastatic Inflammatory Breast Cancer (IBC)- 2012- Celgene Corporation

Sub-investigator. IRB-11007: A Phase I, Multicenter, Open-Label Dose Escalation Study of LDK378, Administered Orally In Adult Patients with Tumors Characterized by Genetic Abnormalities In Anaplastic Lymphoma Kinase (ALK)- 2011-2012-Novartis

Principal investigator (Investigator-initiated). IRB 10-826: prospective collection of Tumor specimens for the establishment of Inflammatory Breast Cancer (IBC) cell lines. Susan Komen Foundation

Principal investigator (Investigator-initiated): NU16B06: Blood-based prognostic biomarkers of Breast Cancer patients (OncoSET Program)

Principal investigator (Investigator-initiated).NU-16B14: I-CURE-1: A phase II, multicenter, single arm study of pembrolizumab combined with carboplatin in patients with circulating tumor cells (CTCs) positive metastatic breast cancer (MBC)-Merck

Principal investigator (Investigator-initiated).NU16B09: A Phase II, open-label study to evaluate denosumab in patients with ER and/or PR positive, HER2 negative metastatic breast cancer (MBC) with bone metastases and detectable circulating tumor cells (CTCs)-Amgen

Principal investigator (Investigator-initiated).NU16B07: A Phase 2 window-of opportunity trial of ipilimumab and nivolumab in metastatic, recurrent HER2- inflammatory breast cancer (IBC). The WIN TRIAL-BMS

Principal investigator (Investigator-initiated). NU18B04: MONARCH-PRECISION PROGRAM: A Prospective, Randomized, Open Label, Phase II study of Abemaciclib combined with fulvestrant vs. abemaciclib in patients with molecularly defined subtypes of hormone-receptor positive (HR+), HER-2 negative metastatic breast cancer (MBC)-Lilly

Principal investigator (Investigator-initiated) NU17: I-STOP: A Phase Ib-II, multicenter, single arm study of Maraviroc combined with carboplatin in patients with CCR5+ triple negative metastatic breast cancer (MBC)-CytoDyn

Principal investigator (investigator-initiated): NU 20B03: Enrichment, Culturing, Characterization and Drug Sensitivity Testing of Circulating Tumor Cells (CTCs) from Patients with Stage IV Breast Cancer

Principal investigator (investigator-initiated): NUB07: A Pilot study of SGT-53 with carboplatin and pembrolizumab in metastatic triple negative inflammatory breast cancer. (SGT)

Research Support:

Current Research Funding

Title: Immune Control of Triple-Negative Breast Cancer by WEE1 Inhibition

Major Goals: To develop more effective approaches to treatment for TNBC

*Status of Support: Active Project Number: W81XWH190106

Name of PD/PI: Bin Zhang

*Source of Support: Department of Defense

*Primary Place of Performance: Northwestern University Project/Proposal Start and End Date: (MM/YYYY) (if available): 03/15/2019 – 03/14/2022

* Total Award Amount (including Indirect Costs): \$1,185,000 * Person Months (Calendar/Academic/Summer) per budget period. 0.36 Calendar

***Title: Unravelling New Cytokine-Mediated Mechanisms to Enhance Response to CDK4/6 inhibition in ER+/HER2-Metastatic Breast Cancer**

Major Goals: To determine the role of cytokines as novel biomarkers for response and elucidate underlying mechanisms.

*Status of Support: Active Project Number: Agmt 10/05/2020

Name of PD/PI: Massimo Cristofanilli

*Source of Support: METAvivor

*Primary Place of Performance: Northwestern University

Project/Proposal Start and End Date: (MM/YYYY) (if available): 10/05/2020 – 10/04/2023

* Total Award Amount (including Indirect Costs): \$500,000 * Person Months (Calendar/Academic/Summer) per budget period. 0.12 Calendar

Title: SIRT3 expression as a novel predictive biomarker of response to palbociclib in ER+/HER2-endocrine-resistant luminal breast cancer

Major Goals: to reveal the SIRT3-dependent mechanisms of drug action for palbociclib that may provide the basis for new interventions to increase clinical benefits associated with CDK4/6 inhibition in otherwise palbociclib-resistant tumors.

*Status of Support: Active Project Number: WI245493

Name of PD/PI: Massimo Cristofanilli

*Source of Support: Pfizer, Inc.

*Primary Place of Performance: Northwestern University

Project/Proposal Start and End Date: (MM/YYYY) (if available): 10/14/2019 – 03/31/2022 (NCE)

* Total Award Amount (including Indirect Costs): \$185,070 * Person Months (Calendar/Academic/Summer) per budget period. 0.12 Calendar

Title: Targeting CysLTR1 in triple negative breast cancer

Major Goals: The goal of this project is to explore CysLTR1 inhibitors alongside agents that stimulate CD8+ T cell activity, including the checkpoint blockade therapies that target PD-1 and PD-L1, which are both in clinical development in treating TNBC.

*Status of Support: Active Project Number: W81XWH2010024

Name of PD/PI: Bin Zhang

*Source of Support: Department of Defense

*Primary Place of Performance: Northwestern University

Project/Proposal Start and End Date: (MM/YYYY) (if available): 07/01/2020 – 06/30/2023

* Total Award Amount (including Indirect Costs): \$1,890,019 * Person Months (Calendar/Academic/Summer) per budget period. 0.36 Calendar

Title: Molecular mechanisms underlying circulating tumor cell aggregation

Major Goals: To determine the molecular mechanisms responsible for CD44 and PAK2-promoted CTC aggregation and lung metastasis and test several CD44/PAK2-inhibiting strategies to prevent and block cancer metastasis.

*Status of Support: Active

Project Number: R01 CA245699

Name of PD/PI: Huping Liu

*Source of Support: NIH/NCI

*Primary Place of Performance: Northwestern University Project/Proposal Start and End Date: (MM/YYYY) (if available): 04/11/2020 – 03/31/2025 *

Total Award Amount (including Indirect Costs): \$2,013,204 * Person Months (Calendar/Academic/Summer) per budget period. 0.24 calendar

***Title: Targeting Posttranslational Modifications in Breast Carcinogenesis**

Major Goals: To determine the impact of interplay between KLF4 and PARP1 in breast tumor progression/metastasis and breast cancer therapy.

*Status of Support: Active (Pending subagreement from Emory University)

Project Number: R01 CA250110

Name of PD/PI: Yong Wan *Source of Support: NIH/NCI

*Primary Place of Performance: Northwestern University

Project/Proposal Start and End Date: (MM/YYYY) (if available): 04/15/2020 – 03/31/2025

* Total Award Amount (including Indirect Costs): \$2,484,055

* Person Months (Calendar/Academic/Summer) per budget period. .60 Calendar

Title: Glycoprotein sialylation of CTC clusters in breast cancer metastasis

Major Goals: This proposal is expected to address three overarching challenges of breast cancer: (1) improve our understanding of breast tumors and how they spread, cluster, and metastasize to distant organs; (2) accelerate the development of new diagnostic and prognostic biomarkers using circulating tumor cells in liquid biopsy; and (3) broaden the potential of innovative therapeutic approaches to target tumor cell clusters and eliminate aggressive metastasis of breast cancer.

*Status of Support: Active

Project Number: W81XWH2010679 Name of PD/PI: Huiping Liu

*Source of Support: Department of Defense

*Primary Place of Performance: Northwestern University

Project/Proposal Start and End Date: (MM/YYYY) (if available): 09/01/2020 – 08/31/2023

* Total Award Amount (including Indirect Costs): \$776,052

* Person Months (Calendar/Academic/Summer) per budget period. 0.24 Calendar

Title: Fellowship in Support of Paolo D'Amico

Major Goals: Support for Paolo D'Amico's training

*Status of Support: Active

Project Number: Agmt 6/29/2020

Name of PD/PI: Massimo Cristofanilli

*Source of Support: American Italian Cancer Foundation

*Primary Place of Performance: Northwestern University Project/Proposal Start and End Date: (MM/YYYY) (if available): 11/20/2020 – 11/20/2021

* Total Award Amount (including Indirect Costs): \$80,000

* Person Months (Calendar/Academic/Summer) per budget period. 0 Calendar

***Title: Fellowship in Support of Carolina Reduzzi**

Major Goals: Support for Carolina Reduzzi's training

*Status of Support: Active

Project Number: Agmt 8/31/2021

Name of PD/PI: Massimo Cristofanilli

*Source of Support: Menarini Silcon Biosystems, Inc.

*Primary Place of Performance: Northwestern University

Project/Proposal Start and End Date: (MM/YYYY) (if available): 10/01/2021 – 09/30/2022

* Total Award Amount (including Indirect Costs): \$100,008

* Person Months (Calendar/Academic/Summer) per budget period. 0 calendar

Title: Targeting posttranslational modifications of B7-H4 in carcinogenesis and therapy

Major Goals: The goal of this project is to determine the impact of interplay between glycosylation and ubiquitination of B7-H4 in breast carcinogenesis and anti-breast cancer therapy

*Status of Support: Active (Pending subagreement from Emory University)

Project Number: R01 CA258765

Name of PD/PI: Yong Wan

*Source of Support: NIH/NCI

*Primary Place of Performance: Northwestern University

Project/Proposal Start and End Date: (MM/YYYY) (if available): 04/01/2021 – 03/31/2026

* Total Award Amount (including Indirect Costs): \$2,758,496

* Person Months (Calendar/Academic/Summer) per budget period. 0.24 Calendar

Title: Targeting posttranslational modifications of CD73 in TNBCs

Major Goals: The goal of this project is to determine the impact of proteolytic regulation of CD73 by the E3 ligase TRIM21 in breast carcinogenesis and as a therapeutic target in breast cancer.

*Status of Support: Active

Project Number: R01 CA258857

Name of PD/PI: Yong Wan (Pending sub-agreement from Emory University)

*Source of Support: NIH/NCI

*Primary Place of Performance: Northwestern University

Project/Proposal Start and End Date: (MM/YYYY) (if available): 04/01/2021 – 03/31/2026

* Total Award Amount (including Indirect Costs): \$3,296,106

* Person Months (Calendar/Academic/Summer) per budget period. 0.24 Calendar

Title: SOD2 functions as an alternative hypoxic histone demethylase in cancer cells

Major Goals: Investigating whether nuclear or acetylated SOD2 are part of a molecular signature predictive of clinical outcomes are the main goals of this project.

*Status of Support: Pending

Project Number: R01 CA260451

Name of PD/PI: Marcelo Bonini

*Source of Support: NIH

*Primary Place of Performance: Northwestern University

Project/Proposal Start and End Date: (MM/YYYY) (if available): 04/01/2022 – 03/31/2027

* Total Award Amount (including Indirect Costs): \$2,282,495

* Person Months (Calendar/Academic/Summer) per budget period. 0.60 Calendar

***Title: Quantitative Multiplexed Pharmacogenetic Profiling as a Path to Expand Precision Medicine in Cancer**

Major Goals: To identify the strongest synthetic lethal events, which will allow us to develop precision medicine treatment strategies that are more effective and less toxic in form of survivalprolonging drugs that are tailored for the individual tumors from patients with all major subtypes of breast cancer.

*Status of Support: Pending Project Number: BC210470

Name of PD/PI: Marc Mendillo

*Source of Support: NIH

*Primary Place of Performance: Northwestern University

Project/Proposal Start and End Date: (MM/YYYY) (if available): 09/01/2021 – 08/31/2023

* Total Award Amount (including Indirect Costs): \$701,798

* Person Months (Calendar/Academic/Summer) per budget period. 0.12 Calendar

Past (Completed) Funding

Please summarize as for current projects: source-type, project title, dates, your role.

Grants and Contracts

Co-Program Leader: Cynvenio Biosystems Inc. SBIR Phase II Topic 293: Developing predictive biomarkers in metastatic breast cancer using liquid biopsy. HHSN261201300073C. 08/27/14-8/26/15; \$30,500. (0.12 calendar)

DOD-DARPA(Tang): Study of a Newly Discovered Immune Cell in the Blood and Evaluation of Its Potential Medical Applications. Sub from Creatv Microtech, Inc. 7/15/14-7/14/16. \$48,000. (0.48 calendar)

NIH(Tang). Circulating Giant Macrophages in MBC: a novel prognostic biomarker of metastasis. Sub from Creatv MicroTech, Inc. 12/01/14-11/30/15. (.6 calendar).

NIH (Shih): Low Cost Blood Molecular Malignancy Test to Detect Recurrences of Breast Cancer. Sub from Lenima. 4/1/15-3/31/16. (1.2 calendar).

Co-Investigator, 0.6 months, Assessing drug response and prognosis in breast cancer using AAVP-based targeted molecular-genetic imaging, Department of Defense (DOD), PI - Arap/Pasqualini, 6/1/2009–6/30/2014, \$6,939,285 (\$1,387,857/year)

Co-Investigator, 0.6 months, Bioengineering and clinical applications of circulating tumor cell chip, The General Hospital Corporation, PI - Herbst, 8/1/2009–7/31/2011, \$1,800,000 (\$450,000/year)

Collaborator, 0.6 months, Gene expression signature of early breast cancer, no cost extension, CA84978-01A1, NIH, PI - Aldaz, 4/6/2001–3/31/2006, \$4,666,942 (\$1,166,735/year)

Collaborator, 0.6 months, Novel technologies for mapping vascular diversity of human cancer, no cost extension, R33 CA103030-01, NIH/NCI, PI - Arap, 3/15/2004–2/28/2007, \$450,537 (\$150,179/year)

Collaborator, 0.6 months, Spousal relationships and pain in metastatic breast cancer, no cost extension, W81XWH-04-1-0425-02, Department of Defense (DOD) U.S. Army Medical Research and Material Command Congressionally Directed Medical Research Programs, PI - Badr, 8/25/2004–9/24/2007, \$404,892 (\$134,964/year)

Collaborator, Regulatory roles for vascular peptidases in angiogenesis, no cost extension, HL081658, NIH/NCI, PI - Pasqualini, 8/1/2005–7/31/2009, \$250,000 (\$50,000/year)

Principal Investigator, 0.12 months, Creation of the rare and aggressive breast cancer, no cost extension, State of Texas, 9/1/2007–8/31/2011, \$4,000,000 (\$2,000,000/year)

Principal Investigator, 0.6 months, Magnetic resonance imaging (MRI) for evaluation of clinical response to induction chemotherapy in breast cancer, CS00-098-1, Susan G. Komen Breast Cancer Foundation, 12/30/1999–6/30/2005, \$244,300 (\$48,860/year)

Collaborator, 0.6 months, The prospective validation of soluble isoforms of ErbB2 (p105-sErb2) and EGFR (110kD-sEGFR) as serum markers of efficacy in hormone sensitive postmenopausal women with metastatic breast cancer treated with either anastrozole alone or in combination with ZD1839 (IRESSA), CA096300005, PRCC/MDACC, PI - Cora, 8/16/2002–7/31/2007, \$30,000 (\$30,000/year)

Principal Investigator, 0.6 months, Phase II trial of depsipeptide in metastatic breast cancer, CA 70172, NCI/CTEP-U01, 8/1/2005–7/31/2007, \$50,000 (\$25,000/year)

Principal Investigator, 0.12 months, First international inflammatory breast cancer conference, 1R13 00451843, NIH/NCI, 12/5/2008–2/28/2010, \$6,450 (\$6,450/year)

Principal Investigator, 0.12 months, Development of Gamma-Secretase inhibitor (R4733) in inflammatory breast cancer, Hoffman-LaRoche, 2/1/2009–1/31/2010, \$75,504 (\$75,504/year)

Program Leader, 2.0 months, Comprehensive Cancer Center Program at Fox Chase P30 CA006927 10/2005 – 06/30/2011

Principal Investigator, 0.12 months, Human breast cancer stem cell surrogates, NCI-APRC 3R01CA138239-02S1, NIH/NCI, 9/30/2009–9/29/2011, \$537,966 (\$268,983/year)

Pending Funding

Please summarize as for current projects: source-type, project title, dates, your role.

Patents & Inventions

Immunivest Corp., Allard JW, Cristofanilli M, Terstappen LWMM. Circulating cancer cells: Early assessment of time to progression survival and response to therapy in metastatic breast cancer, United States, 60/450,519, 10/9/2004, Issued

The Scripps Research Institute, Blixt O, Cristofanilli M, Huflejt ME. Detection, prevention and treatment of breast cancer, United States, 60/629,666, 11/12/2004, Issued

Board of Regents, The University of Texas System co-owns with Introgen Therapeutics, Inc., Cristofanilli M, Krishnamurthy S, Menander K, Hortobagyi GN. Cancer immunotherapy incorporating p53, United States, 60/628,990, 11/17/2004, Issued

Board of Regents, The University of Texas System, Cristofanilli, Mani, Reuben. Detecting EMT markers for circulating cancer stem cells. International application W2011/111103 A2

CCR5 as metastatic target in CTCs in TNBC, TJU-Richard Pestell.

N. MENTORING

Mentorship is a longitudinal, collaborative learning relationship to help the mentee or protégé succeed. Mentoring can be provided within many formats, including one-to-one, small groups, or large group workshops or lectures, which cover any topic directly related to the mentee's career development.

Please list trainees and faculty that you have formally supervised both at home institution(s) and for extramural organizations, etc. Individuals listed in this section should be those supervised in a research, teaching or clinical setting. List only those on whose careers you have had a substantial impact. Do not indicate those for whom you have provided general career advice. This section may be annotated to provide more information.

If this is the candidate's first faculty appointment at WCMC, please list mentoring contributions at institutions where the candidate previously held a faculty position.

Current Mentees:

Duplicate table below as needed. For each mentee, please include the following:

Name: Carolina Reduzzi, PhD

Site/Position: PostDoc

Expected Period (06/2020-current)

- *Investigating the biological role of dual-positive CTCs in MBC*
- *Investigating the role of CTCs clusters in early stage breast cancer*

Manuscripts:

- A. Reduzzi C, et al. *Circulating tumor cell clusters are frequently detected in women with early-stage breast cancer. Cancers (Basel). 2021;13(10):2356.*
- B. Reduzzi C, et al. The curious phenomenon of dual-positive circulating cells: Longtime overlooked tumor cells. *Semin Cancer Biol. 2020 Feb;60:344-350.*

Goals/expected Outcomes: a) functional role of dual-positive CTCs in the metastatic process using in-vivo models; b) prospective investigation on the molecular and biological role of CTCs clusters in non-metastatic BC.
Type of Supervision: Research

Name: Paolo D'Amico, MD

Site/Position: Visiting scientist/medical oncology fellow.

Expected Period (05/2020-11/2021)

Project/Accomplishments: Developing a new method to score HER2 expression in CTCs and evaluate predictive value in MBC.

Presentations at ASCO 2021, SABC 2020 and 2021

Manuscript: a)

Single-cells isolation and molecular analysis: focus on HER2-low CTCs in metastatic breast cancer. *Cancers* 2022 (in press)

Type of Supervision: Research

Past Mentees:

Duplicate table below as needed. For each mentee, please include the following:

Andrew Davis, MD/Medical oncology
fellow/NU

Mentoring Period (072018-06/2020)

Project/Accomplishments:

Manuscripts:

- a) Gerratana L, Davis AA, et al. Emerging Role of Genomics and Cell-Free DNA in Breast Cancer. *Curr Treat Options Oncol.* 2019 Jun 29;20(8):68. doi: 10.1007/s11864-019-0667-9.
- b) Davis AA, et al. Association of a novel circulating tumor DNA next-generating sequencing platform with circulating tumor cells (CTCs) and CTC clusters in metastatic breast cancer. *Breast Cancer Res.* 2019;21(1):137.
- c) Davis AA, et al. Landscape of circulating tumour DNA in metastatic breast cancer. *EBioMedicine.* 2020 Aug; 58: 102914-
<https://doi.org/10.1016/j.ebiom.2020.102914> PMID: 32707446
- d) Jacob S, Davis AA, et al. The Use of Serial Circulating Tumor DNA to Detect Resistance Alterations in Progressive Metastatic Breast Cancer. *Clin Cancer Res.* 2021 Mar 1;27(5):1361-1370.

Current Position: Assistant Professor
of medicine, Breast Medical Oncology,
Washington University

Type of Supervision: Research and
Clinical

Lorenzo Gerratana, MD, PhD
Medical Oncology Fellow University of
Udine/Visiting Scientist at NU
Mentoring period: 06/2017-09/2018

Manuscripts:

- a) Gerratana L, et al. Emerging Role of Genomics and Cell-Free DNA in Breast Cancer. *Curr Treat Options*

Oncol. 2019 Jun 29;20(8):68. doi:
10.1007/s11864-019-0667-9.

b) Gerratana L, et al. Understanding
the organ tropism of metastatic breast
cancer through the combination of
liquid biopsy tools. Eur J Cancer. 2021
Jan;143:147-157. doi:
10.1016/j.ejca.2020.11.005.

c. . Gerratana L, et al. Longitudinal
Dynamics of Circulating Tumor Cells
and Circulating Tumor DNA for
Treatment Monitoring in Metastatic
Breast Cancer. JCO Precis Oncol.
2021 Jun 8;5:943-952. doi:
10.1200/PO.20.00345.

Current Position: Assistant Professor
of medical oncology at the National
Cancer Institute of Aviano (Italy)

Type of Supervision: Research I

***Please list publications, awards, grants, development of new clinical programs or course, and other scholarly products arising directly from the mentoring activity (if applicable); indicate shared publications by numbered entries in this CV.*

Institutional Training Grants and Mentored Trainee Grants *Duplicate table below as needed. Examples include serving as PI or Mentor on T32, K01, K08, K23 or other mentored grants.*

Award Source:
(funding agency, type of grant)
Project title:
Duration of support:
(mm/yyyy-mm/yyyy)

Other mentoring activities *Describe activity; indicate dates.*

O. INSTITUTIONAL LEADERSHIP ACTIVITIES

Please list activities at WCM and affiliates, NYP, and previously employed institutions, including division or department positions, directorships, deanships, chairmanships on major institutional committees.

Chairman, Department of Medical Oncology, Fox Chase Cancer Center, Philadelphia, PA 1/2010-5/2012
Leader, Breast Service Line, Fox Chase Cancer Center, Philadelphia, PA 1/2010-12/2012
Associate Cancer Center Director for Clinical Research, Fox Chase Cancer Center, Philadelphia, PA 1/2010-11/2011
Co-Leader, CCSG Women's Cancer Program, Fox Chase Cancer Center, Philadelphia, PA 1/2010-5/2012
Director of Translational Science, Cancer Genome Institute, Fox Chase Cancer Center, 5/2012-12/2012
Deputy Director of Translational Research, TJUH-KCC, 1/2013-8/2015
Associate Director of Translational Research: 9/15-present
Director of the Robert Lurie Cancer Center OncoSet Precision Medicine Program: 9/15-present
Associate Director of Clinical Research (ad interim): 4/16-9/16

Role(s)/Position

Institution/Location

Dates (yyyy-yyyy)

P. INSTITUTIONAL ADMINISTRATIVE ACTIVITIES

List administrative activities/service to WCM and affiliates, NYP, and previously employed institutions, such as service on Departmental/Divisional committees or membership on institutional committees. Examples of institutional committees include WCM Admissions Committee, Institutional Review Board (IRB), Institutional Animal Care and Utilization Committee (IACUC), Data Safety and Monitoring Committees (DSMC), and Protocol Review and Monitoring Committee (PRMC), Credentials Committee, Patient Quality and Safety, Malpractice Committee.

- Pharmacy and Therapeutics Subcommittee, Representative, The University of Texas, M D Anderson Cancer Center, 1998–2001
- Clinical Research Committee (CRC), Representative, The University of Texas, M D Anderson Cancer Center, 2002–2004
- Study Section Review Committee for Basic Research Projects under the Institutional Research Grants Program, Representative, The University of Texas, M D Anderson Cancer Center, 2002–2005
- Phase I Research Working Group, Representative, The University of Texas, M D Anderson Cancer Center, 2003–2005
- Breast Cancer Tissue Bank Committee, Member, The University of Texas, M D Anderson Cancer Center, 2003–2005
- Preclinical Working Group, Member, The University of Texas, M D Anderson Cancer Center, 2004–2005
- Institutional Research Grant (IRG) Review Panel, Member, The University of Texas, M D Anderson Cancer Center, 2004–2006
- Clinical Research Subcommittee for Faculty Achievement Award, Member, The University of Texas, M D Anderson Cancer Center, 1/2004–12/2004
- Clinical Research Committee (CRC 1), Member, The University of Texas, M D Anderson Cancer Center, 1/2006–9/2009
- Selection Committee for the 3rd AACR Outstanding Investigator Award for Breast Cancer Research, 2010
- Executive Committee of Staff (ECOS), Member, Fox Chase Cancer Center, 2010–2012
- Executive Committee of Research (ECOR), Member, Fox Chase Cancer Center, 2010 – 2012
- Clinical Council, Member, Fox Chase Cancer Center, 2010 – 2012
- Faculty Practice Plan Executive Council, Member, Fox Chase Cancer Center, 2010 – 2012
- Revenue Enhancement Committee, Fox Chase Cancer Center 2010 – 2012
- Integrative Care Initiative Committee, Fox Chase Cancer Center 2011 – 2012
- Corporate Agenda Planning Committee, Fox Chase Cancer Center 2011 – 2012
- Metastatic Breast Cancer Working Group, WCP at the Fox Chase Cancer Center 2011 –10/2012
- Clinical Research Task Force, Leader, Fox Chase Cancer Center, 2011 – 2012
- Clinical Research Committee- Fox Chase Cancer Center- 2/2010-12/2012
- Executive Leadership Committee-Kimmel Cancer Center: 2013-2015
- Comprehensive Status Program- KCC; 2014-2015
- Executive Leadership Committee-Robert Lurie Cancer Center-9/2015-current
- CRO Governance Committee-RLCC: 9/15-current
- Cancer Center Executive Council-RLCC: 9/15-current
- Member of the Quantitative and Data Science Core Advisory Committee 1/2016-present
- Member of the Proteomic Core Advisory Committee 5/2016-present

<i>Name of Committee</i>	<i>Role (i.e., member, secretary, etc.)</i>	<i>Dates (yyyy-yyyy)</i>
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Q. EXTRAMURAL PROFESSIONAL RESPONSIBILITIES

Leadership in Extramural Organizations

<i>Organization</i>	<i>Role (i.e., officer, secretary, chair, etc.)</i>	<i>Dates (yyyy-yyyy)</i>
The IBC International Consortium Precision Medicine Exchange Consortium (PMEC) Oversight Committee	Founder and President Chair	2014-present 9/17-11/20
International Society of Liquid Biopsy (ISLB)	Chair of the Admission Committee	8/17-Present
International Society of Liquid Biopsy ODAC-FDA Committee	President Standing Membership	8/18-Present 7/2018-current
Merck Breast IDMC G1 Therapeutic	Chair Steering Committee	10/2018-Present 5/18-present
Sermonix AACR YA	Steering Committee Grant review member	5/19-present 2019
AZ NCCN YA2021	Chair IDMC-CAPItello studies Grant Review	5/19-current 2021

Service on Boards and/or Committees

Regional

<i>Name of Committee</i>	<i>Role (i.e., member, fellow, etc.)</i>	<i>Organization Institution/Location</i>	<i>Dates (yyyy-yyyy)</i>
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National

<i>Name of Committee</i>	<i>Role (i.e., member, fellow, etc.)</i>	<i>Organization Institution/Location</i>	<i>Dates (yyyy-yyyy)</i>
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International

<i>Name of Committee</i>	<i>Role (i.e., member, fellow, etc.)</i>	<i>Organization Institution/Location</i>	<i>Dates (yyyy-yyyy)</i>
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Grant Reviewing/Study Sections

<i>Role(s)</i>	<i>Organization Name</i>	<i>Dates (yyyy-yyyy)</i>
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Editorial Activities

Journal Reviewing/ad hoc reviewing

<i>Journal / Organization Name</i>	<i>Dates (yyyy-yyyy)</i>
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Editor/Co-Editor

Books / Textbooks / Journals / Organization Name

Dates (yyyy-yyyy)

Editorial Board Membership

Board / Organization Name

Dates (yyyy-yyyy)

R. INVITATIONS TO SPEAK/PRESENT

Regional:

- The medical management of primary and metastatic breast cancer, UT Southwestern Medical School, Dallas, TX, 3/2001
- The medical management of primary and metastatic breast cancer, UT Southwestern Medical School, Dallas, TX, 3/2001
- New frontiers in the management of primary and metastatic breast cancer, Grand Rounds, Beth Israel Hospital-Harvard Medical School, Boston, MA, 3/2002
- The evolution in the medical management of primary breast cancer, Grand Rounds, Henry Ford Hospital, Detroit, MI, 3/2002
- Inflammatory breast cancer (IBC): Patterns of recurrence and micrometastatic homing, 29th San Antonio Breast Cancer Symposium, San Antonio, TX, 12/2006
- Inflammatory breast cancer update, Grand Rounds, M. D. Anderson Cancer Center, Orlando, FL, 1/2007
- Molecular therapies of cancer, Academy of Molecular Imaging (AMI) Meeting, American Society of Nuclear Cardiology, Miami Beach, FL, 1/2007
- The complexity of inflammatory breast cancer (IBC): The M. D. Anderson Cancer Center Mission, Palm Beach Event, Cancer Seminar, The University of Texas M. D. Anderson Cancer Center, Palm Beach, FL, 2/2007
- Circulating tumor cells (CTCs) in breast cancer patients: Prognosis, prediction and beyond, Grand Rounds, Dartmouth Hitchcock Medical Center, Lebanon, NH, 3/2007
- Targeting inflammatory breast cancer, Tumor Conference, Halifax Medical Center, Daytona Beach, FL, 2/2008
- Circulating tumor cells in breast cancer therapy, Breast Cancer Program, Roswell Park Cancer Institute, Buffalo, NY, 3/2008
- Inflammatory breast cancer: Diagnostic and treatment challenges, Grand Rounds, Presbyterian Healthcare Hospital, Albuquerque, NM, 3/2008
- Circulating tumor cells, Biological Basis in Breast Cancer Conference, CBCE, San Francisco, CA, 7/2008
- Inflammatory breast cancer (IBC): Diagnosis, biology and treatment. Helen Graham Cancer Center, Newark, DE, 5/5/2010
- Creating a state-of-the-art comprehensive breast center to improve patient care, enhance workflow and efficiency. Keynote Speaker, ACI Breast Centers of Excellence Conference, Philadelphia, PA, 6/2010
- The prognostic and predictive value of enumeration and molecular characterization. ADAPT/2nd Annual Circulating Tumor Cells Conference, Philadelphia, PA, 9/2011
- Facing Breast Cancer: New Advances in the Treatment of IBC. Radiation Fellows Lecture. 10/31/2013.
- PBCC Workshop Presentation: Conference. Harrisburg, PA 10/15/2013.

- Einstein Hospital-Montefiore New York, NY- Grand Rounds 4/3/2013.
- 2015. June 12: Hosting: Inaugural Jefferson Inflammatory Breast Cancer Community Conference. Thomas Jefferson University. Phila. PA

National:

- Chemotherapy in early breast cancer, 1st Annual Palm Beach Cancer Symposium, Boca Raton, FL, 2/1999
- The prognostic value of tumor size in axillary node-negative breast cancer: A retrospective analysis of breast cancer patients treated at The University of Texas M . D. Anderson Cancer Center with >10 years follow up, Annual Meeting of the American Society of Clinical Oncology, Atlanta, GA, 5/1999
- Circulating tumor cells: A prognostic or predictive factor?, 5th International Symposium on Minimal Residual Cancer, San Francisco, CA, 9/2005
- Predictive and prognostic tools for managing metastatic breast cancer-prognostic and predictive value of circulating tumor cells in metastatic breast cancer: Clinical applications and research opportunities, San Antonio Breast Cancer Conference - Satellite Symposium, San Antonio, TX, 12/2004
- Circulating tumor cells in breast cancer: Challenges and opportunities for the detection of microscopic disease, 13th Annual Radiation Workshop, Round Top, TX, 4/2005
- Lapatinib/Paclitaxel for inflammatory breast cancer, Chemotherapy Foundation Symposium XXV, Mount Sinai School of Medicine, New York, NY, 11/2007
- New frontiers in micrometastasis research: A transatlantic perspective, Transatlantic Research and Innovation Symposium on Cancer, Carnegie Institute, Washington, DC, 10/2008
- The potential role of circulating tumor cells, Breast Cancer: Current Controversies and New Horizons Conference, Harvard Medical School, Boston, MA, 7/2009
- A phase II multicenter, double-blind, randomized trial to compare anastrozole plus gefitinib with anastrozole plus placebo in postmenopausal women with hormone receptor positive metastatic breast cancer, 44th Annual Meeting of the American Society of Clinical Oncology, American Society of Clinical Oncology, Chicago, IL, 5/2008
- Circulating tumor cells, RTOG Semi-Annual Meeting, Radiation Oncology Group, San Diego, CA, 1/2008
- Circulating tumor cells as predictive and prognostic markers, 1st Annual North American Symposium on Personalized Therapies for Breast Cancer, The Oncology Learning Center, Miami, FL, 1/2008
- Clinical utility of circulating tumor cells, Circulating Tumor Cells: Detection, Diagnostics, Prognostics and Treatment Conference, National Cancer Institute at Frederick, Bethesda, MD, 9/12/2009
- Inflammatory breast cancer: Finding a cure by achieving early detection and treatment, CSG WEST 62nd Annual Meeting - Health Forum, Council of State Governments-WEST, Santa Fe, NM, 10/5/2009
- Systemic approaches to inflammatory breast cancer, 11th Annual Lynn Sage Breast Cancer Symposium, Robert H. Lurie Comprehensive Cancer Center of Northwestern University, Chicago, IL, 10/14/2009
- CTCs in breast cancer: Advanced tools for tailored therapy? Methods workshop speaker, 2010 Annual Meeting of the American Association for Cancer Research, Washington, DC, 4/5/2010
- Circulating tumor cells (CTCs) in breast cancer: Use of novel diagnostics to define the metastatic process. CHI Biomarker World Congress 2010, Philadelphia, PA, 5/8/2010
- ASCO Annual Meeting, Chicago, IL. "Beyond Trastuzumab and Lapatinib-New Options in HER2 Positive Breast Cancer." 5/31/2013. "Adjuvant Chemotherapy of Breast Cancer Improving Patient Selection and Understanding Benefits and Risks"
- Prognostic and predictive value of enumeration and molecular characterization. Speaker, Session Chair and Scientific Advisory Board Member. Molecular Med Tri-Con/Annual Circulating Tumor Cells for Cancer Detection, Diagnosis, Prognosis and Treatment Meeting, San Francisco, CA, 2/21/2012

- 2021. ASCO meeting 2021: Oral presentation:” Overall survival with palbociclib + verall survival with palbociclib + fulvestrant in women with hormone receptor–positive, human epidermal growth factor receptor 2–negative advanced breast cancer: Updated analyses from PALOMA-3 6/2/2021

International

- Medical management of advanced breast cancer and new treatments for breast cancer, 5th International Colloquium of Oncology and Hematology, Oaxaca, Mexico, 6/2001
- Clinical application of circulating tumor cells in breast cancer, 43rd Annual Meeting of the Japan Society of Clinical Oncology Luncheon Seminar, Nagoya Congress Center, Nagoya, Japan, 10/2005
- Microscopic disease in breast cancer: Clinical applications and research opportunities, International Scientific Symposium IGF-MD Anderson, IGF, Paris, France, 9/2006
- New technologies for tumor cell detection in blood and bone marrow, 31st ESMO Congress, Istanbul, Turkey, 10/2006
- Trastuzumab-based regimens in primary breast cancer: Targeted therapy and beyond, XXIII Annual Meeting of the National Cancer Institute of Mexico (INCAN), Puerto Vallarta, Mexico, 2/2006
- Circulating tumor cells in metastatic breast cancer: Toward personalized treatments, 6th International Symposium on Minimal Residual Cancer, University Medical Center Hamburg-Eppendorf, Hamburg, Germany, 9/21/2007
- Inflammatory breast cancer: Diagnostic and therapeutic challenges, The Visiting Speakers Program in Oncology, Universite de Montreal, Montreal, Canada, 11/2007
- The biological information obtainable from circulating tumor cells, 11th International Conference Primary Therapy of Early Breast Cancer, St. Gallen Oncology Conferences, St. Gallen, Switzerland, 3/12/2009
- Bevacizumab: New schedules and new combinations, 1st International Meeting on New Drugs in Breast Cancer, AIM Group, Rome, Italy, 4/21/2009
- Circulatory tumor cells in metastatic breast cancer: Site-specific risk stratification and HER-2 Systemic therapies for IBC: From chemotherapy to targeted therapies: State of the art and future perspectives, AIOM Inter-Regional Conference, AIOM, Cagliari-Villasimius, Italy, 5/6/2009
- Minimal burden to breast cancer: How to approach, 11th Milan Breast Cancer Conference, IEO European Institute of Oncology, Milan, Italy, 6/18/2009
- Circulating tumor cells in breast cancer: Advanced tools for tailored therapy?, 7th International Congress on Minimal Residual Cancer, University of Athens, Athens, Greece, 9/7/2009
- Inflammatory breast cancer: Biology and treatment, Meet the Professor 5th Advanced Course on Breast Cancer, Accademia Nazionale di Medicina, Modena, Italy, 11/2/2009
- Inflammatory and locally advanced disease, Speaker and Session Chair, 4th International Consensus Conference on Neoadjuvant Treatment of Primary Breast Cancer, Biedenkopf, Germany, 9/2010
- Medical treatment of IBC: Present & Future, 2nd International Inflammatory Breast Cancer Conference, Marseille, France, 10/11/2010
- Circulating tumor cells and their prognostic and predictive value in breast cancer, VIII GEICAM International Symposium, A Coruna, Spain, 3/18/2011.
- Circulating tumor cells: Where are we? 2nd International Meeting on New Drugs in Breast Cancer, Rome, Italy, 10/2011
- CTCs: Evolving concepts for personalized therapy in breast cancer. AIOM, National Medical Oncology Conference, Bologna, Italy, 11/2011
- Evolving concepts in the management of metastatic breast cancer. 1st Joint Conference KFSHD-RPCI-SCF-ASCO on Management of Colon, Breast and Lung Cancer: Update and Future Prospects, Dammam, Saudi Arabia, 3/2012

- China 88 Xintiandi Shanghai. Defining the role of circulating tumor cells (CTCs) in the liquid phase of epithelial tumors.” Immunican Shanghaie Conference. Fudan Hospital, 9/13/2013.
- 9th International Symposium on Minimal Residual Cancer (ISMRC 2013) EMT and CTC. Paris, France. 9/21/2013.
- 5th Symposium Primary Systemic Treatment in the Management of Operable Breast Cancer. Cremora Italy. Workshop on Circulating Tumor Cells in Routine Clinical Setting. 10/3/2013.
- 16th Milan Breast Cancer Conference. Innovation in Care and Research. Umberto Veronesi, Chairman 6/26/2014.
- 3rd International Meeting on New Drugs in Breast cancer. Rome, Bastianelli Congress Center. November 13-15, 2013.
- San Antonio Breast Symposium. “Inflammatory Breast Cancer Diagnosis, Treatment and Biology”. December 10th-12th. 2013
- 4th IBC Conference-Belgium. IBC Meeting AntWerp 2014. HER2 Directed Therapy. Ongoing Clinical Trials in IBC. 5/6/2014.
- 2014 Annual Meeting of CSCO Xiamen, China. Improve Standardized Treatment Level, Broaden International Prospective. New Targeted Therapy in Breast Cancer. 9/18/2014.
- 2nd International Symposium ACTC. Advances in Circulating Tumour Cells from Basic Research to Clinical Practice. “CTC in breast cancer 2004-2014: Clinical Value Revised” Rethymnon, Crete, Greece, 10/4/2014
- 2018: ESMO Annual Symposium: Presidential session presentation: Overall survival (OS) with palbociclib plus fulvestrant in women with hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2_) advanced breast cancer (ABC): Analyses from PALOMA-3. 10/20/2018

S. BIBLIOGRAPHY

1. Peer-reviewed Research Articles:

1. **Cristofanilli M**, Bryan WJ, Miller LL, Chang AY, Gradishar WJ, Kufe DW, Hortobagyi GN. Phase II study of adozelesin in untreated metastatic breast cancer. *Anticancer Drugs* 9:779-82, 1998.
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5. Non-peer-reviewed Research Publications:
6. Case Reports (*optional, or list 10 best*):
7. Guidelines (*if not listed above*):
8. In review (*manuscripts submitted or in preparation – list separately*):

9. **Abstracts** (*optional, list 10-20 best or most recent only*):

Please choose

10. Other (*media, podcasts, etc.*): Letters to the Editor

1. **Cristofanilli M**, Singletary ES, Hortobagyi GN. Inflammatory breast carcinoma: The sphinx of breast cancer research. J Clin Oncol 15(22):381-383, 2004.
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Recognition of Exemplary Service during the COVID-19 Pandemic

Please complete if relevant or DELETE entirely.

Faculty across all missions are encouraged to provide below an optional narrative, not to exceed 1 page, of their performance of unusual and exemplary service during the COVID-19 pandemic. This may include such activities as increased clinical service or redeployment to areas outside of their basic expertise, transformation of laboratory activities in support of COVID-19-related research, development of new educational curricula to enable remote electives and on-line learning.