

**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: Milana V. Dolezal, M.D., M.Sci

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

POSITION TITLE: **Clinical Associate Professor of Medicine in the Stanford School of Medicine, Division of Oncology**

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 applicabl e)	Completion Date MM/YYYY	FIELD OF STUDY
<b>Undergraduate:</b> University of Maryland, College Park, MD	BS	06/1992	Senatorial Scholarship and House of Delegates Scholarship, Biology
<b>Gibbon MD/PhD scholar: PhD Candidate:</b> Thomas Jefferson Graduate School, Philadelphia, PA	MSci	1994-1997	Department of Biochemistry Neurocysticercosis/Oncogenesis work in Ecuador
<b>Medical degree from Jefferson Medical School</b> Philadelphia, PA	MD	1995-1999	Foerderer Scholarship for International Study on HIV education in Africa (1999)
<b>Internal Medicine Residency</b> University of Southern California, Los Angeles, CA		1999-2002	Elective rotation examined hormone resistance and HER2Neu overexpression in Breast Cancer.
<b>Hematology/Oncology Fellow</b> UCLA Medicine and Researcher at Jonsson Comprehensive Cancer Center, Los Angeles, CA		2002-2005	Investigated role of Notch and Wnt pathways in the early events of hematopoiesis. Responsible for several IRB submissions. Board certification in Hematology and Oncology.
<b>Genentech Drug Development Clinical Fellow</b> South SF, CA		2005-2006	Clinical Scientist Biooncology Therapeutics unit. Lead clinical scientist and medical monitor for the Herceptin registry and work on adjuvant Herceptin breast cancer joint analysis filing (BLA) and post marketing commitments (RegistHER)

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**A. Personal Statement**

My work in cancer research began as a teenager doing bench research at NCI, NIH as a work-study student while at the University of Maryland. My personal connection to cancer began in my 20’s, when my Czech grandmother, who raised me, died of metastatic breast cancer. She passed one month prior to my starting an MD/PhD program. Since then, and for more than 20 years, I’ve held various oncology roles across research, industry/clinical trials, and community clinical care.

As a full-time community oncologist, I have demonstrated leadership in several areas with past directorships within Sutter in Research/Clinical trials and Cancer Survivorship/Supportive care at two different institutions (Alta Bates Summit and CPMC). I was the Sutter representative in the oncology clinical trials consortium for the East SF Bay with a Directorship of Research for several years. In addition to that cooperative group trial role with a unified Sutter Northern California IRB, I was able to engage in the recruitment of cutting-edge industry-sponsored targeted therapy clinical trials. Such trials include the practice changing CDK inhibitor Monalessa trials for breast cancer treatment. I was recognized as a top enroller in clinical trials in the Sutter network for several years in a row. I’ve enrolled young breast cancer patients on fertility preservation trials at USCF and published on outcomes.

After 12 years as a clinician in the Sutter network including eight years in the East Bay (as Physician site lead of five Heme/Onc MDs along with three directorships and GI tumor board head), I transitioned to Stanford HC in at satellite site in Emeryville in January 2022. In that role, I spearheaded the first clinical trial at our community site (NCT05929768) and we continue to slowly build our cancer portfolio. I am currently at Stanford as a Clinical Associate Professor with a full time busy 4 day a week clinical hematology/oncology practice. I actively participate in our bi-weekly Breast Cancer CRG/clinical research group for trial review, discussion and selection. Taking care of the whole person and cancer survivorship is very important to me and continue to develop Cancer Survivorship programs, educational roundtables and implementing a Multidisciplinary sexual health clinic for female anatomy breast cancer survivors in the next few months.

On the clinical trials front, I wrote the white paper for the FDA BCIRG 006 phase 3 clinical trial filing for an additional adjuvant Trastuzumab approval while at Genentech. My industry experience spanned several phases of clinical trials including 2 NME- new molecular entity combination trials utilizing small molecular inhibitors and targeted antibody drug conjugates/ADC’s. I created a “Herceptin escape” clinical trial looking at mechanisms of resistance to HER2 breast cancer therapies combining the ADC TDM1 and PI3K inhibitors. As the clinical lead of the PI3K/mTOR diagnostic program, I led a breast cancer tumor working group and ran phase 1 and 1b clinical trials programs across all tumor types.

**B. Positions, Scientific Appointments, and Honors**

**1/2024-Current Clinical Associate Professor of Medicine in the Stanford School of Medicine, Division of Oncology with a full-time community practice in Emeryville, CA**

\*Susan G Komen keynote speaker and Komen board member

\*Spearheaded the first clinical trial at our community site (NCT05929768)

**1/2022-Current Medical Oncology and Hematology Attending Stanford Oncology Emeryville, CA Subspecialty in women’s cancers and breast cancer management/survivorship**

**9/2009-12/2021 Sutter Health Hematology/Oncology**

**1/2018- 12/2021 Attending at Pacific Hematology Oncology Associates CPMC (California Pacific Medical Center)**

\*Medical Director of Cancer Survivorship and Supportive Services Program

\*Member of Breast cancer leadership/advisory board and Cancer committee

**9/2009- 12/2017 Medical Oncology and Hematology Attending at Alta Bates Summit Medical Center (ABSMC)**

2010-2014 Clinical site lead/Practice group Leader of 5 heme/onc physicians

2010-2017; Medical Director of Colorectal Cancer Program, Chair of biweekly GI tumor board.

2012-2017 Medical Director of Cancer Survivorship program of ABSMC

## **2014-2017 Sutter Health Research Executive committee NCI Consortium East Bay Region Lead with over 100 cooperative cancer trials**

2010-2012 Member of Quality Committee for hospital and East Bay Medical Foundation group

\*Spearheaded QOPI quality oncology practice certification 2016

\*Spearheaded cancer survivorship program development and implementation including grant support for children-adult cancer transitions clinic development and community primary care partnership and Medical Director of Cancer Survivorship program of ABSMC

**\*Principal investigator on several Breast and Colorectal/GI clinical trials**

**2009 Stanford School of Medicine Adjunct Clinical Instructor:** Breast cancer clinic attending

**2008-2009 Genentech Assistant-Associate Medical Director BioOncology Exploratory Clinical Development**

Responsible for many trials spanning early development (phase Ia's and phase Ib's) to phase II including 2 NME

Medical monitor and protocol development responsibilities, clinical input into key combination development strategies

Clinical lead of PI3K diagnostic program, lead of breast cancer tumor working group.

**2006-2008 Genentech Assistant Medical Director BioOncology Late Development:**

Filing co-lead clinical scientist for the adjuvant Herceptin breast cancer BCIRG 006 BLA,

primary clinical overview/white paper author, and additional adjuvant breast cancer BLA's work.

Clinical lead of adjuvant PMC's (post-marketing commitments including QTc and drug-drug interaction studies)

Drug safety team with PSUR review, Investigator brochure and annual report development.

## **SCHOLARSHIP/HONORS/AWARDS:**

2005-2007 Sponsored athlete on the Zoom elite triathlon team

2005 Team USA triathlon age-group division World championships

2004 Ironman finisher

2003 Tour of Hope rider across the USA with Lance Armstrong for cancer awareness and encouraged clinical trial participation

2003 Speaker at NIH as Tour of Hope representative and former NIH researcher

2000-2002 Research Scholarly Committee of USC Department of Medicine

2001 Triathlon and cycling coach for Leukemia Lymphoma Society TNT

1999 Foerderer Scholarship for International Study on HIV education in Africa

1995-1997 President of Medical Students for Choice at Jefferson Medical College

1994-1997 Gibbon Scholar MD/PhD Thomas Jefferson Medical College and Graduate School

1991-1992 President of Best Buddies chapter at the University of Maryland (matching college students in one-to-one friendships with mentally disabled people)

1990-1991 Vice president of Best Buddies chapter at the University of Maryland

1988-1992 Senatorial Scholarship and House of Delegates Scholarship

1988-1992 General Honors Program at the University of Maryland

## **C. Contributions to Science**

For more than 20 years, I've held various oncology roles across research, industry/clinical trials, and community clinical care.

As a young adult at the NIH and at Stanford prior to entering a MD/PhD program, I co-authored hematology/pathology And cancer biology papers:

1. Sander CA, Yano T, Krameris AM, Clark HM, **Dolezal MV**, Longo DL, Jaffe ES and Raffeld M. Association of p53 mutations with histologic transformation of follicular lymphoma and chronic lymphocytic leukemia. Blood 11/92 Vol 80, No.10: 1758.
2. Yano T, Sander CA, Clark HM, **Dolezal MV**, Jaffe ES and Raffeld M. Clustered mutations in the second exon of MYC gene in sporadic Burkitt's lymphoma. Oncogene 6/1993; Vol. 8: 2741-2748.
3. **Dolezal MV**, Kamel OW, Van de Rijn M, Cleary ML, Sibley RK and Warnke RA. Virus-Associated Hemophagocytic Syndrome Characterized by Clonal Epstein-Barr Virus Genome. Am J Clin Pathol 2/1995; Vol 103, No. 2: 189-194.
4. Kamel OW, Chang PP, Hsu FJ, **Dolezal MV**, Warnke RA and Van de Rijn M. Clonal VDJ Recombination of the Immunoglobulin Heavy Chain Gene by PCR in Classical Hodgkin's Disease. Am J Clin Pathol 101/1995; Vol. 104, No. 2: 419-423.
5. Natkunam Y, Soslow R, Matolesy A, **Dolezal M**, Bhargava V, Knowles D and Warnke R. Phenotypic and Genotypic Characterization of Follicular Lymphomas Showing Histologic Changes in Follow-up. Appl Immunohist & Mol Mophol. 2004; 12:97-104.

**During medical school, I had an interest in the intersection of infectious disease and cancer. Thus, I did a rotation in Ecuador with a world expert in Neurocysticercosis and published in Spanish and English:**

1. Del Brutto OH, **Dolezal MV**, Castillo PR, Garcia HH. Neurocysticercosis and Oncogenesis. Archives of Medical Research 31 (2000): 151-155.

**While enduring over 80-hour work weeks during internal medicine residency and hematology/fellowship, I wrote a book chapter along with ASH posters/co-authored papers:**

1. Ganapati U, Tan HT, Lynch M, **Dolezal M**, de Vos S and Gasson JC. Modeling Notch Signaling in Normal and Neoplastic Hematopoiesis: Global Gene Expression Profiling in Response to Activated Notch Expression. Stem Cells 2007; 25: 1872-1880.
1. Schmitt IA, **Dolezal M**, Press, MF. Progression from Hormone-Dependent to Hormone-Independent Breast Cancer. Chapter in Hormones, Genes and Cancer edited by Brian Henderson, Bruce Ponder and Ronald Rose. Oxford University Press, Inc., pp. 255-272, 2003.

**After hematology/fellowship, I had a keen interest in translational research and clinical trials especially with a focus on targeted agents in breast cancer treatment. Thus, I pursued a drug development fellowship at Genentech.**

Notable scientific contributions included the adjuvant Herceptin joint analysis filing (BLA) and co-lead clinical scientist for the adjuvant BCIRG 006 BLA and primary author of the FDA white paper. As an assistant to associate medical director in research and early drug development, I was the clinical lead of the PI3K diagnostic program and lead of breast cancer tumor working group and wrote ASCO/ECCO/ESMO/AACR posters and presentations for our key opinion leaders and principal investigators at academic sites including:

1. Amler, L...**Dolezal M** .... Her Pathway Gene Expression Analysis in a Phase 2 Study of Gemcitabine+Pertuzumab vs. Gemcitabine+Placebo in Patients with Platinum-Resistant Epithelial Ovarian Cancer: Low Her 3 Expression May Identify a Novel Patient Subgroup. Presented at ASCO 2008 Poster #4483.
2. Kaufman PA, Mayer M, Paik S...**Dolezal M** registHER: Trastuzumab-based Taxane or Vinorelbine treatment selection in patients with HER2 positive metastatic breast cancer: patient characteristics and preliminary outcomes. Presented at the 29<sup>th</sup> Annual San Antonio Breast Cancer Symposium in San Antonio, Texas; December 14-17, 2006. SABCS Poster #2066.
3. Wagner, A.. **Dolezal M**.... A First-in-Human Phase 1 Study to Evaluate the Pan-PI3K Inhibitor GDC-0941 Administered QD or BID in Patients with Advanced Solid Tumors. Oral Presentation at ASCO 2009 #3501
4. Von Hoff, DD...**Dolezal MV**.... A first-in-human Phase I study to evaluate the pan-PI3K inhibitor GDC-0941 administered QD or BID in patients with advanced solid tumors. Oral Presentation at ECCO 2009 #1205
5. Kristeleit, R...**Dolezal MV** .... A phase I study evaluating the pharmacokinetics (PK) and pharmacodynamics (PD) of the oral pan-phosphoinositide-3-kinase (PI3K) inhibitor GDC-0941. Oral Presentation at ECCO 2009 # 1204

**After transitioning to full time community oncology clinical practice in 2009, my overall philosophy of care has been more patient-facing program support/development and less podium focused.** I started two Cancer Survivorship programs within the Sutter system and presented posters at ASCO Cancer Survivorship Symposiums:

1. **Dolezal MV**, Pristina M .... Psychosocial distress screening and the survivorship care plan in the community oncology setting. Poster presentation #206 ASCO Cancer Survivorship Symposium 2016 *Journal of Clinical Oncology* 34, no. 3\_suppl (January 2016) 206-206.
2. **Dolezal MV**, Leong V.... Monitoring oral anti-cancer therapy adherence in cancer patients using a web-based application guided communication compared with nurse counseling in a community cancer center. Poster presentation #88 ASCO Cancer Survivorship Symposium 2017. *Journal of Clinical Oncology* 35, suppl 55 (January 2017)

**At Stanford, I subspecialize in breast cancer care and triple negative breast cancer unmet needs while maintaining a busy 4 day a week clinical hematology/oncology practice in the SF East Bay community (Emeryville).**

In addition, I continue to support Cancer Survivorship Multi-Disciplinary Care via the creation of a Sexual Health MultiD clinic. In terms of peer national/international education, I've posted several breast cancer talks on Vu medi with >5400 views. National/International Publications include:

1. Cristofanilli, Massimo, **Dolezal MV** .... Phase 1b/II Study of Leronlimab Combined with Carboplatin in Patients with CCR5+Metastatic Triple-Negative Breast Cancer (mTNBc) Abstract CT233 August 2020 AACR annual meeting, Cancer Research 80
2. Cristofanilli, Massimo, **Dolezal MV** ... Phase 1b/II Study of Leronlimab Combined with Carboplatin in Patients with CCR5+Metastatic Triple-Negative Breast Cancer (mTNBc) ASCO June 4-8, 2021 Annual meeting
3. **Dolezal MV**, Pegram M. Breast Cancer Index (BCI) results from a HER2 low breast cancer community cohort of operable stage I-II hormone receptor positive (HR+) breast cancer. San Antonio Breast Cancer Symposium Poster Session 5; PO5-13-04 12/8/2023
4. Pestell, RG, Cristofanilli, M, **Dolezal MV**. Observed survival following treatment with Leronlimab in patients with metastatic triple-negative breast cancer (mTNBC). ESMO Breast Cancer Poster Session 369P; Munich Germany 5/15/2025
5. **Dolezal MV**. Multidisciplinary sexual health pilot clinic for female anatomy cancer patients. 15<sup>th</sup> European Congress on Menopause May 14-16, 2025 Valencia, Spain P236 San Antonio Breast Cancer/SABCS 12/2025

1) Prolonged survival following PD-L1/PD-1 immune checkpoint inhibitor therapy after leronlimab induced PD-L1 upregulation on cancer-associated macrophage-like cells and circulating tumor cells in patients with metastatic or locally advanced triple-negative breast cancer; Dolezal et al Abstract Number: 747 Presentation Number: PS5-02-30 Poster Presentation Date/Time: Friday, December 12, 2025, 12:30 PM - 2:00 PM

2) Circulating Tumor DNA (ctDNA) Monitoring of High-Risk Breast Cancer Patients: A Retrospective Descriptive Analysis in a Community Setting; Thompson, C and Dolezal, M Abstract Number: 220 Presentation Number: PS4-03-17 Poster Presentation Date/Time: Thursday, December 11, 2025, 5:00 PM - 6:30 PM

- **Manuscript submitted** (first author) to Journal of Precision Oncology; 9/2025; Title; Sustained Disease-Free Survival in Metastatic Triple-Negative Breast Cancer Following CCR5 Antibody Leronlimab and Atezolizumab. A Case Study