CURRICULUM VITAE

Personal Data

Name: Miguel Angel Villalona-Calero, M.D.

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Date of Birth: January 1, 1961

Work History

| 09/15-Present | Chief Scientific Officer and Deputy Director, Miami Cancer Institute, Miami, Forida. |
|---------------|---|
| 05/15-08/15 | Associate Director Translational Research, The Ohio State University Comprehensive Cancer Center, Columbus Ohio. |
| 05/10-05/15 | Director, Division Medical Oncology, Dept of Internal Medicine, The Ohio State University College of Medicine and Public Health, Columbus, Ohio |
| 05/10-05/15 | Section Chief Arthur James Cancer Hospital, The Ohio State University, Columbus Ohio. |
| 09/07-05/15 | Professor of Medicine, Arthur G. James Comprehensive Cancer Center and Richard J. Solove Research Institute, and Department of Internal Medicine, The Ohio State University College of Medicine and Public Health, Columbus, Ohio |
| 09/07-05/15 | Professor of Pharmacology, Department of Pharmacology, The Ohio State University College of Medicine and Public Health, Columbus, Ohio |
| 07/04-08/15 | Co-Medical Director of Clinical Research Unit, Arthur G. James Cancer Hospital, Columbus, Ohio |
| 10/02-09/07 | Associate Professor of Medicine and Lung Cancer Physician, Arthur G. James Cancer Hospital and Department of Internal Medicine, The Ohio State University College of Medicine and Public Health, Columbus, Ohio |
| 04/99-10/02 | Assistant Professor of Medicine and Lung Cancer Physician, Arthur G. James Cancer Hospital and Department of Internal Medicine, The Ohio State University College of Medicine and Public Health, Columbus, Ohio |
| 07/95-04/99 | Research Physician, Institute for Drug Development, Cancer Therapy and Research Center, San Antonio, Texas |
| 08/92-08/94 | Physician and Director Chemotherapy Service, Pickens County Hospital, Carrollton, Alabama |

Academic Appointments

| 01/16 | Professor Dept of Medicine, Family Medicine and Community Health Florida international University, Miami, Florida. |
|------------------------|---|
| 05/10-05/15 | Dorothy M. Davies Chair in Cancer Research, The Ohio State University Comprehensive Cancer Center- Arthur G. James Cancer Hospital and Richard J. Solove Research Institute |
| 05/10-05/15 | Director, Division Medical Oncology, Dept of Internal Medicine, The Ohio State University College of Medicine and Public Health, Columbus, Ohio |
| 2007-2015 | Professor of Pharmacology, Department of Pharmacology, The Ohio State University College of Medicine and Public Health, Columbus, Ohio |
| 2007-2015 | Professor of Medicine, Department of Internal Medicine, The Ohio State University College of Medicine and Public Health, Columbus, Ohio |
| 2005-2007 | Associate Professor of Pharmacology, Department of Pharmacology, The Ohio State University College of Medicine and Public Health, Columbus, Ohio |
| 2002-2014 | Director of Solid Tumor Experimental Therapeutics, Arthur G. James Comprehensive Cancer Center and Richard J. Solove Research Institute, The Ohio State University, Columbus, Ohio |
| 2002-2007 | Associate Professor of Medicine with Tenure, Arthur G. James Comprehensive Cancer Center and Richard J. Solove Research Institute, and Department of Internal Medicine, The Ohio State University College of Medicine and Public Health, Columbus, Ohio |
| 1999-2002 | Assistant Professor of Medicine, Arthur G. James Comprehensive Cancer Center and Richard J. Solove Research Institute, and Department of Internal Medicine, The Ohio State University College of Medicine and Public Health, Columbus, Ohio |
| 1996-1999 | Clinical Assistant Professor, University of Texas Health Science Center, San Antonio, Texas |
| 1995-1996 | Instructor of Medicine, University of Texas Health Science Center, San Antonio, Texas |
| Education | |
| Graduate/Und | ergraduate: |
| 1980-1985 | Medical School, Universidad Nacional Pedro Henríquez Urena (U.N.P.H.U.), Santo Domingo, Dominican Republic |
| 1977-1980 | Pre-medical School, Universidad Nacional Pedro Henriquez Urena (U.N.P.H.U.), Santo Domingo, Dominican Republic |
| Fellowships: 2001-2002 | NHMA Health Policy Leadership, New York University, Robert Wagner Graduate School of Public Service |
| 1994-1995 | Drug Development, Institute for Drug Development, University of Texas Health Sciences Center at San Antonio. |
| 1990-1992 | Medical Oncology, Roswell Park Cancer Institute, Buffalo, New York |

1989-1990 Medical Oncology, University of Minnesota Hospital & Clinics, Minneapolis, MN

Internship and Residency:

1986-1989 Internal Medicine, Kings County Hospital Center, State University of New York Health

Sciences Center at Brooklyn (DMC)

Health Service:

2013

1985-1986 Instituto Oncologico H. Pieter, Santo Domingo, Dominican Republic

Honors and Awards

Professional Recognitions:

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Fellow. American Association for the Advancement of Science.

Recognition Plaque for Valuable Service in the Field of Oncologic Research and Dedication to the Patients with Cancer. Universidad Nacional Pedro Henriquez Urena, Health Sciences Center, School of Medicine and the UNPHU Alumni Society, Santo Domingo, Dominican Republic.

2008 Outstanding Example of Translational Research. N01 CM-62207. National Cancer Institute.

2008 Recognition Plaque for International Role in Medical Oncology, Dominican Society of

Hematology/Oncology, Punta Cana, Dominican Republic

The V Foundation/American Association for Cancer Research Translational Cancer Research

Award for Scientific Excellence in the Fight Against Cancer.

2003 Fray Anton de Montesinos Award to the Dominican Professional of the Year in The United

States, Alumni Association Universidad Autonoma de Santo Domingo, Inc., Queens, NY

1999 Fellow, American College of Physicians/American Society of Internal Medicine, Philadelphia, PA

Junior Faculty Awards

1996 ASCO/AACR Methods in Clinical Cancer Research Workshop Travel Award, Park City Utah

1995 The Clinical Pharmacology of Anticancer Agents Workshop Travel Award, Lansdowne Virginia

Fellowship Awards:

1995 National Cancer Institute, Minority Scientist

1995 Travel Grant Award, American Association of Cancer Research

1991 Travel Grant Award, American Society of Clinical Oncology

Residency Recognition:

1987 Second Honorable Mention, Annual Case Report Competition, Brooklyn, N.Y.

Medical School:

1986 First Prize, VII Congress of the Dominican Association of Pediatric Research, Garcia Cohen

Foundation, Santo Domingo, DR.

1986 Elected to represent U.N.P.H.U. Medical School, IV Student Investigational Congress, San Juan,

Puerto Rico.

1985 Magna Cum Laude

1984 Elected among the class for a Sub-Internship in U.S.A (Internal Medicine, Danbury Hospital,

Danbury, CT) Sponsored by the university and given under open contest to the best two students

of the class.

Member of the Honor Board of the Medical School, Average G.P.A. 3.41/4.0, and third in the

class.

Pre-medical School:

1977-1980 Member of the Honor Board of the University (U.N.P.H.U), Average G.P.A. 3.66/4.0, and third

in the class

Administrative/Professional Development Training

Nov 7-19, 2010 Harvard School of Public Health. Leadership Development for Physicians in Academic Health Centers

Grant support:

Principal Investigator:

a. Federal/State Agency

1. 2011-2015 National Cancer Institute, N01-CM-2011-00070. HHSN261201100070C

"Early Therapeutics Development with Phase II Emphasis"

Role: Principal investigator \$6,047,915 direct costs.

2. 2010-2015 NIH/NCI R01. CA152101

Targeting somatic homologous recombination in solid tumors.

Role: Principal Investigator. \$2,556,482.

3. 2012-2015 National Cancer Institute. T32 CA165998-01

Training Hematology and Oncology Fellows in Clinical Research.

Role: Principal Investigator, \$870,166 direct costs.

4. 2009-2012 NIH/NCI ACTNOW Clinical trial 8472. Modification to N01-CM-62207ABT-888 as

Monotherapy and in Combination with Mitomycin C in Patients with Solid Tumors with

Deficiency in Homologous Recombination Repair.

Role: Principal investigator, \$754,737.

5. 2006-2011 National Cancer Institute, N01-CM-62207

"Early Therapeutics Development with Phase II Emphasis"

Role: Principal investigator \$5,074,367.

6. 2004-2008 National Cancer Institute, R21 CA108157 "Biomodulation of capecitabine by docetaxel in non-small cell lung cancer" Role: Principal Investigator, \$612,950 National Cancer Institute, R21 CA101360 "TNF Blockade in Pancreatic Cancer 7. 2003-2007 Patients". Role: Principal Investigator, \$665,276 8. 2002-2006 National Cancer Institute, R21 CA92956"Phase II randomized trial of Sequentially Administered CPT-11 and Mitomycin C in Patients with Advanced Esophageal and Stomach Cancer." Role: Principal Investigator, \$656,376 9. 2001-2003 National Cancer Institute, R21 CA91547 "Suramin to enhance efficacy of paclitaxel and carboplatin in NSCLC" Role: Co-Principal Investigator, P.I. Jessie Au, \$500,000 10. 1997-2003 National Cancer Institute, Research Scientist Mentored Career Development Award K01 CA76970 "Translational Research in Lung Cancer" Role: Principal Investigator, \$810,912

11. 1995-1998 National Cancer Institute, Long-Term Minority Investigator Research Supplement, U01 CA69853-01S1 "Phase I Clinical Trials of Anticancer Agents"
Role: Principal Investigator, \$154,717

b. Peer-Reviewed Foundations/Associations

1. 2005-2010 The V Foundation-American Association for Cancer Research Translational Research Grant "Evaluating the genetics and Pharmacodynamics of EGFR Blockade in African Americans with Lung Cancer".

Role: Principal Investigator \$300,000 plus \$300,000 matching funds

c. Institutional

4- 2012-2014. Pelotonia Idea Award. Combined EGFR and BRAF blockade in Patients with Advanced Malignancies and BRAF Mutant Tumors. \$150,000 direct costs

Co-Investigator:

- a. Federal/State Agency
- 2014-2015 National Cancer Institute UM1CA186712-01
 "Experimental Therapeutics of Anti-cancer Agents with Phase I Emphasis"
 Role: Solid Tumor lead. P.I. Mike Grever, \$4,200,000
- 2. 2008-2013 National Cancer Institute R21 CA121582A
 "MR-predictive-assay in pre-operative lung cancer therapy: response/resectability"
 Role: Co-Investigator, P.I. J. Grecula. \$750,000
- 3. 2014-2015 National Cancer Institute K12 CA133250-04 "Translational Training Grant in Experimental Therapeutics" Role: Faculty Mentor, PI: J Byrd \$827,653
- 4. 2010-2014 1U01CA152758-01. MIRNAS/UCRS: "Biomarkers for Cancer Risk, Tumor Detection,

Progression and Treatment."

Role: Co-Investigator, PI: Croce, 1.2 calendar months

5. 2014-2016 NIH/NCI R21CA181291: "Discovery of Homologous Recombination DNA Repair Deficiency in Lung Tumor"

Role: Co-investigator/Mentor, PI: Duan, 0.36 calendar months. \$422,981.00

6. 2009-2014 T32 CA009338-35: "Oncology Training Grant"

Role: Mentor, PI: Caligiuri \$442,656

7. 2008-2013 National Cancer Institute, UO1 CA76576-01

"Phase I trials of anti-cancer agents",

Role: Co-Investigator, P.I., Mike Grever \$1,921,216

8. 2008-2013 National Cancer Institute K12. "Translational Training Grant in Experimental

Therapeutics"

Role: Faculty Mentor, PI: J Byrd \$827,653

9. 2008-2013 National Institute of Neurological Disorders and Stroke, K01NS059575

"Combination of Cliengitide and Oncolytic HSV: a toxicology study for brain tumors"

Role: Mentor. P. I. Balveen Kaur, \$2,214,430

10. 2003-2009 State of Ohio Biomedical Research and Technology Transfer Trust Fund"Comprehensive Program for the Prevention, Detection and Treatment of Lung Cancer"Role: Co-investigator, P.

I., Mike Caligiuri, \$8,000,042, cost sharing \$15,226,121

11. 2003-2008 National Cancer Institute, UO1 CA76576-01

"Phase I trials of anti-cancer agents",

Role: Co-investigator, P.I., Mike Grever \$1,921,216

12. 2002-2004 National Cancer Institute, R21 CA92958

"Preoperative Treatment of Lung Cancer with rhuMab VEGF"

Role: Co-investigator, P.I. Greg Otterson, \$500,000

13. 1999-2000 Comprehensive Cancer Center, Arthur James Cancer Hospital and R. Solove Research Institute Research Award "Development of a screening strategy for hypomethylating chemotherapeutic

agents"

Role: Co-Principal Investigator, \$12,500, P. I. Greg Otterson.

d. Industry (31 total):

- 2009-2014 Oncolytics. "Phase II Study of Intravenous Administration of Reovirus Serotype 3 –
 Dearing Strain (REOLYSIN®) in Combination With Paclitaxel and Carboplatin in
 Patients With Metastatic or Recurrent Non-Small Cell Lung Cancer Who Have KRAS or
 EGFR Activated Tumors". Role: Principal Investigator \$217,180
- 2. 2011-2014 Imclone. Phase 1 Study of IMC-CS4, a Monoclonal Antibody Targeted to the CSF-1 Receptor (CSF-1R), in Subjects with Advanced Solid Tumors Refractory to Standard Therapy or for Which No Standard Therapy is Available. \$424,816.
- 3. 2013-2015 Glaxo/SKB. A Phase II study of the BRAF inhibitor dabrafenib as a single agent and in

combination with the MEK inhibitor trametinib in subjects with BRAF V600E mutation positive metastatic (stage IV) non-small cell lung cancer \$446,170

 2009-2012 Glaxo/Smith Kline. An Open-label, Multicenter, Phase I/II Study of Pazopanib in Combination with Paclitaxel in First-line Treatment of Subjects with Stage IIIB wet/IV Non-small Cell Lung Cancer.

Role: Institutional Principal Investigator \$202,404

- 5. 2005-2012 Genentech, Inc. "A phase II randomized study of OSI-774 in African American patients with advanced and previously treated non-small cell lung cancer". Role: Principal Investigator, \$92,365.52
- 6. 2009-2011 AstraZeneca. "A phase II, double blind, randomized study to assess the efficiency of AZD6244 (Hyd-Sulfate) when given in combination with docetaxel, compared with placebo to AZD6244 in combination with docetaxel in patients with KRAS mutation positive locally advanced or metastatic non small cell lung cancer (stage III-IV)". Role: Institutional Principal Investigator. \$79,180
- 7. 2009-2011 Bayer Healthcare Pharmaceuticals. IST000389

"A Phase II Study of Single Agent Sorafenib In Non-small cell lung cancer patients who never smoked or were former light smokers".

Role: Principal Investigator \$119,583

8. 2008-2010 Glaxo/SmithKline "A Double-Blind, Randomized, Placebo-Controlled Phase III Study to Assess the Efficacy of recMAGE-A3 + AS15 Antigen-Specific Cancer Immunotherapeutic as Adjuvant Therapy in Patients with Resectable MAGE-A3-Positive Non-Small Cell Lung Cancer". \$154,360
Role: Institutional Principal Investigator

9. 2005-2009 Immunogen Inc.

"A Phase I, Open Label, Dose Escalation Study of Weekly Dosing with BB-10901 Followed by a Phase II Efficacy Expansion"

Role: Institutional Principal Investigator, \$163,559

10. 2004-2007 Kosan Biosciences; Principal Investigator.

"Phase 1 Dose Escalation Trial to Evaluate the Safety, Pharmacokinetics, and Pharmacodynamics of KOS-1584 in Patients with Advanced Solid Tumors;

Role: Institutional Principal Investigator \$279,480

11. 2004-2006 OSI Pharmaceuticals

"A Randomized Phase II Study of Single Agent Erlotinib (Tarceva™, OSI-774) versus Standard Chemotherapy in Patients with Previously Untreated Advanced NSCLC and a Poor Performance Status"

Role: Institutional Principal Investigator, \$45,500

12. 2003-2004 Millenium Pharmaceuticals

"A randomized, Multicenter, Open-Label, Phase 2b Study of VELCADE TM alone and VELCADETM plus Irinotecan in Patients with Relapsed or Refractory Colorectal Carcinoma"

Role: Institutional Principal Investigator, \$117,120

130. 2003-2004 Hoffman-La Roche, Kosan Biosciences

"Phase 2 Study of KOS-862, Administered Intravenously Weekly for 3 Weeks Every 4 Weeks, In Patients with Non-Small Cell Lung Cancer Who Have Progressed Following Therapy for Advanced or Metastatic Disease"

Role: Institutional Principal Investigator, \$133,150

14. 2002-2003 Pharmacia/Celgene

"A Phase I and Pharmaco-Biological Study of Thalidomide and Celecoxib as modulators of irinotecan's anticancer activity"

Role: Principal Investigator, \$225,000

15. 2001-2003 Hoffmann-La Roche Inc.

"A Phase II Study of Capecitabine and Docetaxel in previously Treated Non-Small Cell Lung Cancer Patients"

Role: Principal Investigator, \$165,500

16. 2001-2003 Immunex Inc.

"Phase I and biological study of etanercept and weekly docetaxel in patients with advanced solid tumors"

Role: Principal Investigator, \$96,000

17.2000-2002 Isis Pharmaceuticals

"A pilot trial of ISIS 3521, an antisense inhibitor of Protein Kinase C α , combined with Gemcitabine and Cisplatin chemotherapy in patients with advanced cancer (Part 1), or advanced, previously untreated non-small cell lung cancer (Part 2). Role: Institutional Principal Investigator, \$77,500 total

18. 2001-2002 Immunex Inc.

"A phase I feasibility study and a randomized double blinded and placebo controlled phase III study comparing etanercept, cisplatin and etoposide with cisplatin and etoposide in patients with extensive stage and chemotherapy naïve small-cell lung cancer.

Role: Principal Investigator, \$320,000

19. 2001-2002 Immunex Inc.

"A phase II Study of Etanercept and Gemcitabine in Patients with Advanced Stage and Chemotherapy-Naïve Pancreatic Adenocarcinoma"

Role: Principal Investigator, \$156,000

20. 2000 Ortho Biothec Inc.

"Randomized study of Procrict® (epoietin alfa) vs. no Procrit on clinical outcomes in chemotherapy-naïve, stage IIB/IV non-small cell lung cancer (NSCLC) patients receiving chemotherapy"

Role: Institutional Principal Investigator, \$ 102,000

21, 1999-2000 Rhone Poulenc Rorer

"A phase I and pharmacokinetic study of docetaxel administered weekly to patients with advanced malignancies"

Role: Principal Investigator, \$108,000

22. 1999-2000 Hoffmann- La Roche Inc.

"A phase I study of capecitabine in combination with weekly docetaxel in patients with advanced solid tumors"

Role: Principal Investigator, \$131,138

23. 1995-1997 Hoffmann-La Roche Inc.

"A phase I study of Capecitabine (Ro 09-1978) when combined with paclitaxel in patients with advanced solid tumors"

Role: Principal Investigator, \$210,687

24. 1995-1996 Neurobiological Technologies Inc.

"The Effect of Human Corticotropin-Releasing Factor on Peritumoral Brain Edema - Pilot Study"

Role: Principal Investigator, \$51,019

25. 1995-1996 Pro-Neuron, Inc.

"Phase I Trial of a Fixed Dose of PN401 as a Rescue Agent for Escalating Doses of 5-Fluorouracil (5-FU) in the Treatment of Patients with Cancer Refractory to Standard Therapy: weekly x 3 schedule"

Role: Principal Investigator, \$98,610

26. 1996 Knoll Pharmaceutical Company

"Phase I study to determine the safety of LU 103793, every other day x 3, given every 3 weeks to patients with malignant solid tumors"

Role: Principal Investigator, \$73,360

27. 1996-1997 Knoll Pharmaceutical Company

"Phase I study to determine the safety of LU 79553, every day x 5 days, given every 3 weeks to patients with malignant solid tumors"

Role: Principal Investigator, \$391,870

28. 1996-1997 Hoffmann-La Roche Inc.

"A phase I/II study of Capecitabine (Ro 09-1978) when combined with paclitaxel in patients with breast cancer"

Role: Principal Investigator, \$180,830

29. 1996-1997 Pharma Mar

"A phase I study of ET-743, every day x 5 days, every 21 days"

Role: Principal Investigator, \$187,325

30. 1994-1996 Knoll Pharmaceutical Company

"Phase I study to determine the safety of LU 103793 as a five-minute IV infusion, daily x 5, given every 3 weeks to patients with malignant solid tumors"

Role: Principal Investigator, \$119,040

31. 1995-1997 Ilex Oncology

"Phase I trial of Crisnatol Mesylate on an increasingly Prolonged Continuous Infusion Schedule in Patients with Refractory Malignancies"

Role: Principal Investigator, \$178,925

Certifications

| 1985- | Diplomat of the Educational Commission for Foreign Medical Graduates. |
|------------------|---|
| | No.378-646-4, Cert No. A6137, valid indefinitely |
| 1987- | Diplomat of the Federal Licensure Examination, ID # 610101901 |
| 1993-2003 | American Board of Internal Medicine No. 127932 |
| 1995-2005 | ABIM/Subspecialty Board of Medical Oncology |
| 2003-2013 | American Board of Internal Medicine, Recertification |
| 2005-2015 | ABIM/Subspecialty Board of Medical Oncology, Recertification |
| 2014-2024 | ABIM/Subspecialty Board of Medical Oncology, Recertification |
| | Meeting MOC Requirements |
| 2008-2010 | ACLS Provider, American Heart Association |
| 2010- | Leadership Development for Physicians in Academic Health Centers, Harvard School of Public Health |
| <u>Licensure</u> | |
| 1999- | State of Ohio License Registration No. 75950 |
| 1995- | Texas License Registration No. J7716 (inactive) |
| 1997- | Florida License Registration No. ME 75284 |
| 1992-1995 | Alabama License No. 16812 (inactive) |
| 1990-1992 | New York Limited Permit No. P47870 (inactive) |
| 1989-1992 | Minnesota License No. 32357 (inactive) |
| | |

Community Service

Keynote Address Speaker, Naturalization Ceremony, Statehouse, Columbus, OH, 2007

Knights of Malta's Medical Missioner, Juncalito & Santiago, Dominican Republic, 2006-2012

Mentorship/Academic Advising

a- Mentorship Activities

Methods in Clinical Cancer Research.

American Association of Cancer Research/American Society of Clinical Oncology

Vail, Colorado.

Role: Faculty, Group Leader and Speaker 2008-2011

Minorities in Cancer Research Professional Advancement Roundtable:

Navigating the road to a successful career in cancer research.

American Association for Cancer Research

Role: Mentor 2007, 2008, 2012 (co-chair)

OSU Hematology-Oncology Fellowship Steering Committee

b- Mentees

Faculty Level of advisees/Current Position

Tanios Bekaii-Saab, MD Young Faculty/Assistant Professor Hem-Onc OSU,

2003-present GI-Oncology Program Leader

Role: Mentor and Career Advisor

Paul Monk, MD Young Minority Faculty/Assistant Professor, Hem-Onc GU Program OSU

2006-present Role: Career Advisor (Minority)

Yiqing Xu, MD, PhD Young Faculty/Assistant Professor, Maimonides, NY

2003-2008 Role: Career Advisor

Roger Briesewitz, PhD Young Faculty/Assistant Professor Dept of Pharmacology OSU

2006-present Role: Advisory Committee Member/Mentor

Wenrui Duan, PhD Post Doctoral Researcher/Research Scientist OSU. (2010-present))

1999-present Role: Mentor, Career Advisor and Laboratory Supervisor

Kari Kendra, MD Young Faculty/ Assistant Professor Hem-Onc, Melanoma Program OSU

2006-present Role: Career Advisor

Mitch Phelps, PhD Young Faculty/Assistant Professor School of Pharmacy 2008-present Role: Career Advisor and RC2 Application Mentor

Bhuvana Ramaswamy, MD Young Faculty/Assistant Professor Hem-Onc, Breast Program OSU,

CO- Medical Director Clinical Trilas Office OSUCCC

2008-present Role: Career Advisor and Clinical Trials Mentor

Amir Mortazavi, MD Young Faculty/Assistant Professor Hem-Onc, GU Program OSU

2008-present Role: Career Advisor and K Grant Application Mentor

Balveen Kaur, PhD Young Faculty/Assistant Professor Neurosurgery, OSU

2007-present Role: K01 mentor

Abraham Jacob, MD Young Faculty/Assistant Professor Department of Otolaryngology, OSU

2007-2011 Role: K01 mentor

David O'Malley, MD Young Faculty/Assistant Professor Department of GYN-Oncology, OSU

2007-present Role: Career Development Advisor/Clinical Trials Development

Kamal Pohar, MD Young Faculty/Assistant Professor Department of Urology, OSU

2009-2010 Role: Career Development advisor, K12 application mentor

Muller Fabbri, MD, PHD Research Scientist, Department of Cancer Genetics, OSU

2010-2011 Role: K08 mentor

Feyce Peralta, MD Assistant Professor, Anesthesia, Northwestern University (Minority)

2006-present Role: Mentor and Career Advisor

Meng Welliver, MD Assistant Professor, Radiation Oncology, OSU

Role: Mentor and career advisor 2012-present

Associate Professor, OSU (Minority) Patrick Nana-Sinkam

Role: Career advisor 2012-present

Level of advisees/Current Position **Fellows**

Jim Maher, MD Fellow in Hematology-Oncology/Private Practice Ohio

2001-2002 Role: Continuity Clinic Mentor

Tamila Kindwall-Keller, MD Fellow in Hematology-Oncology/Assistant Professor, Case Western

2002-2004

Regina Crawford, MD

Fellow in Hematology-Oncology, OSU/ Assistant Professor, Duke Univ.

Role: Continuity Clinic Mentor and Advisor for Academic Development

(Minority)

Role: Continuity Clinic Mentor 2003-2005

Padma Nadella, MD Fellow in Hematology/Oncology, OSU/Assistant Professor, Emory

Role: Continuity Clinic Mentor and Career Advisor 2005-2007

Haghighat, MD Fellow in Hematology-Oncology/Private Practice California

2006-2007 Role: Continuity Clinic Mentor

Haiming Ding, MD, PhD Postdoctoral Fellow/Research Scientist Department of Radiology

2003-2005 Role: Laboratory Supervisor

Fellow in Hematology-Oncology/Chief Fellow OSU Elaine Lam, MD

2007-2010 Role: Continuity Clinic Mentor and Advisor for Academic Development

Hiram Perez Rivas, MD Fellow in Pulmonary OSU (Minority)

2012-Role: Mentor and career advisor

Erica Bell, PhD Postdoctoral Researcher, Radiation Oncology OSU

Research Mentor

Postdoctoral Researcher, Medical Oncology, OSU Arjun Karvala, PhD

Role: Research Mentor and Laboratory Supervisor

Students

1995 - 1996

Matt Campos Co-Path Medical Student OSU (Minority)

Role: Mentor and Career Advisor 2009

Luis Rodriguez UTHSC San Antonio, TX. Graduated Medical School 1996. Residency

Internal Medicine and Oncology Washington University/Medical

Oncologist South Texas (Minority)

c- Doctoral Student (Dissertation Advisor)

Yu-Chieh Wang 2007 - 2008 Exploitation and Mechanistic Validation of Drug-combination Strategies to Overcome EGFR-inhibitor resistance in NSCLC cells. The Ohio State

University, Columbus, OH.

d- Doctoral Student (Dissertation Committee Member)

Haiyan Qin. Downmodulation of Cyclin D1 by Fhit: a putative tumor suppressor pathway,

The Ohio State University, Columbus, OH.

e- Doctoral, pre-candidacy (Advisor)

Yu-Chieh Wang. 2006 - 2007

Enhancing the antitumor activity of EGFR inhibitors with HDAC inhibitors by simultaneously targeting Akt and NR4A1 signaling in non-small-cell lung

cancer, The Ohio State University, Columbus, OH.

Memberships and Associations

American Association for the Advancement of Science (Fellow)

American Association for Cancer Research

American College of Physicians/American Society of Internal Medicine

American Society of Clinical Oncology

Cancer and Leukemia Group B

International Association for the Study of Lung Cancer

National Hispanic Medical Association

Ohio State University Comprehensive Cancer Center

Sociedad Dominicana de Hematologia y Oncologia.

Committees Membership a. Institutional

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|---|---|-------------|
| | Chairman, Pathology Review and Infection Control Committees | |
| | Picken's County Hospital, Carrollton Alabama | 1992-1994 |
| | Member, Pain Committee | |
| | University of Texas Health Science Center | 1996-1997 |
| | Alternate Member, Scientific Review Committee | |
| | Cancer Therapy & Research Center | 1997-1999 |
| | Co-director, Women and Minorities Committee | |
| | The Ohio State University Comprehensive Cancer Center | 1999-2002 |
| | Member, Executive Committee | |
| | The Ohio State University Comprehensive Cancer Center | 1999-2006 |
| | Member, Coordinating Committee | |
| | The Ohio State University Comprehensive Cancer Center | 1999-2006 |
| | Member Clinical Scientific Review Committee | |
| | The Ohio State University Comprehensive Cancer Center | 1999-2008 |
| | Member Clinical Value Enhancement Committee | |
| | The Ohio State University Hospital | 1999-2006 |
| | Member Operating Committee MD/PhD program | |
| | The Ohio State University | 2001-2009 |
| | Minority Recruitment Coordinator MD/PhD program | |
| | The Ohio State University | 2001-2009 |
| | Member Hematology/Oncology Fellowship Steering Committee | |
| | The Ohio State University, Dept of Medicine | 2001-presen |

Member Clinical Trials Office Steering Committee

The Ohio State University Comprehensive Cancer Center 2002-present

Member Clinical Portfolio, Outreach and Affiliations Working Group

The Ohio State University Comprehensive Cancer Center 2003-2008

Member, Women and Minorities Committee

The Ohio State University Comprehensive Cancer Center 2003-2006

Member Clinical Trials Office Medical Director Search Committee

The Ohio State University Comprehensive Cancer Center 2005-2006

Chair Search Committee Molecular Pharmacogenetics Program

The Ohio State University Comprehensive Cancer Center 2005-2007

Member Search Committee Hematology/Oncology Director

The Ohio State University Department of Medicine 2007

Member Advisory Committee Appointments, Promotion and Tenure

The Ohio State University, College of Medicine 2007-2010

Member, James Medical Staff Administrative Committee

Arthur James Cancer Hospital 2008-2009

Member, OSU Internal Advisory Committee, Program Project "Discovery of Novel

Anticancer Agents of Diverse Natural Origin", PI. D. Kinghorn

The Ohio State University 2008-present

b. National/International

American Society of Clinical Oncology

Methods in Clinical Cancer Research. (ASCO/AACR)

Role: Faculty, Group Leader and Speaker 2008-2011

Member, Task Force on Health Disparities

& Work Force Diversity
 Member, Grants Selection Committee
 Roster of Cancer Experts
 2003-2005
 2004-2005
 2005-present

Developmental therapeutics Scientific Committee-

Clinical Pharmacology & Experimental Therapeutics

abstracts review committee 2013, 2014
Track Leader 2015

American Association for Cancer Research

Member Program Committee, Phase I, II, III Adult Clinical Trials 2003

Member, Program Committee Clinical Research Section

Phase II and Phase III Adult Clinical trials 2008-2009

Member, Scientific Review Committee.

Second AACR Conference on the Science of Cancer Health Disparities in Racial/Ethnic

Minorities and the Medically Underserved 2008-2009

Co-Chairman AACR 2009 Annual Meeting

Organizing Committee 2008-2009

Methods in Clinical Cancer Research. (ASCO/AACR)

Role: Faculty, Group Leader and Speaker 2008-2011 Council Member, Minorities in Cancer Research 2010-2013

Member, Scientific Review Committee,

Third AACR Conference on the Science of Cancer Health Disparities in Racial/Ethnic

2011-2012

Minorities and the Medically Underserved 2010 Co-Chair MICR Symposium AACR 2011 Annual Meeting 2010-2011

(Selection Committee member 2013)

Co-Chair 2012 Jane Cooke Wright Lectureship

Co-Chair Fourth AACR Conference on the Science of Health Disparities

In Racial/Ethnic Minorities and the Medically

Underserved 2011 Co-Chair MICR Professional Advancement Roundtable 2013

Member Scientific Review Committee Clinical and Translational Research Fellowships

2015-2016

Cancer Prevention and Research Institute of Texas

Member Translational and Clinical Scientific Review Committee 2009-2013

Cancer and Leukemia Group B

Member 1999-present Thoracic Core Committee member 2010-present

Food and Drug Administration

Office of Orphan Products Development, Department of Health & Human Services,

Grant Reviewer 1998

National Cancer Institute

Manpower and Training Review Subcommittee,

(ad-hoc reviewer)1999, 2000Clinical Oncology Review Session, Ad Hoc member2003, 2005Permanent Member Clinical Oncology Review Session2007-2009Cancer Center Support Grant Reviewer2010-2011

NCI Investigational Drug Steering Committee,

Member2006-presentMember, Clinical Trial Design Task Force2006-2008Member, Conflict of Interest Task Force2006-2008Member, Gap Analysis Task Force2007-2009Co-Chair, DNA repair Task Force2008-2011Member Coordinating Committee2011- presentCo-Chair2012-2014

Clinical Trials Advisory Committee (CTAC)

Ad Hoc member 2011 Appointed member 2012 Member re-appointment 2015

National Cancer Centers Network Fatigue Panel

Member Fatigue Guidelines Development Task Force 2003

National Institute of Health

Reviewer Loan Repayment Program Proposals 2003

Southwest Oncology Group

Member, Lung Cancer Study Group 1998-1999

Theradex

Medical Auditor, Cancer Center Site Visit.

NCI Surgical Branch and NCI, Developmental Therapeutics Clinic. 2012

Journals

Editorial Board:

Journal of Clinical Oncology (2007-2015)

Cancer Chemotherapy and Pharmacology (2007-current)

Clinical Cancer Research (2010-2013)

Frontiers in Oncology (2014-current) (Associate Editor)

Ecancermedicalscience (2014-current)

Reviewer:

British Journal of Cancer

Cancer Research

Cancer

Cancer Chemotherapy and Pharmacology

Cancer Genetics and Cytogenetics

Chemotherapy

Clinical Breast Cancer

Clinical Cancer Research

Investigational New Drugs

International Journal of Cancer

Journal of Clinical Oncology

Journal of Clinical Pharmacology

Lung

Molecular Cancer Therapeutics

Pharmacology and Therapeutics

Cancer Prevention Research

Springerplus

Meeting Organization Leadership Role

| 201 | 0-2011 | Co-Chairman AACR Fourth AACR Conference on the Science of Health Disparities |
|-----|---------|--|
| | | In Racial/Ethnic Minorities and the Medically Underserved |
| 200 | 08-2009 | Co-Chairman of 2009 American Association of Cancer Research Meeting |
| 200 | 7-2009 | OSU CCC/Zangmeister Cancer Center ASCO review |
| 200 | 7-2008 | Grand Rounds OSU Comprehensive Cancer Center |
| 200 | 04-2005 | Grand Rounds OSU Comprehensive Cancer Center |
| 199 | 98 | Multimodality Therapy of Lung Cancer. San Antonio |

Institutional and NCI-Sponsored Protocols (Chair/Institutional-Chair):

| 1999-2001 | OSU 9947: A phase I study of CPT-11 in combination with mitomycin-C in patients with advanced malignancies. Principal Investigator (Completed) |
|-----------|---|
| 1999-2000 | OSU 9957: A phase I study of capecitabine in combination with weekly docetaxel in patients with advanced solid tumors. Principal Investigator. (Completed) |

OSU 9987: Phase I/II Study of G3139, a bcl-2 antisense oligonucleotide, combined with paclitaxel for the treatment of recurrent small cell lung

cancer. Co-Investigator (Completed)

| 1999 | OSU 9975: Randomized study of Procrit® (epoietin alfa) vs. no Procrit on clinical outcomes in chemotherapy-naïve, stage IIB/IV non-small cell lung cancer (NSCLC) patients receiving chemotherapy. Institutional Chair. (Completed) |
|------|--|
| 2000 | OSU 0009: A pilot trial of ISIS 3521, an antisense inhibitor of Protein Kinase C α , combined with Gemcitabine and Cisplatin chemotherapy in patients with advanced cancer (Part 1), or advanced, previously untreated non-small cell lung cancer (Part 2). Principal Investigator . (Completed) |
| 2000 | OSU 9985: Phase I and clinical pharmacologic study of inhaled Doxorubicin in adults with advanced solid tumors affecting the lungs. Co-Principal Investigator (Completed) |
| 2000 | NCI 290, OSU 00H0057: A phase I study of BMS-214662 and Paclitaxel in Patients with Advanced Malignancies. Institutional Chair. (Completed) |
| 2000 | NCI 2250, OSU 00H0224: A Phase I/II Study of Carboplatin/Paclitaxel/Suramin Chemotherapy in Non-Small Cell Lung Cancer. Principal Investigator (completed, R21 funding) |
| 2000 | 00H0314, OSU 0023: Phase I and Biological Study of Etanercept and Weekly Docetaxel in Patients with Advanced Solid Tumors. Principal Investigator (completed) |
| 2001 | OSU 0026: A Phase II Study of Capecitabine and Docetaxel in |
| | Previously Treated Non-Small Cell Lung Cancer Patients. Principal Investigator (completed). |
| 2001 | Previously Treated Non-Small Cell Lung Cancer Patients. Principal |
| 2001 | Previously Treated Non-Small Cell Lung Cancer Patients. Principal Investigator (completed). 01H044, OSU 0036: A phase I feasibility study and a randomized double blinded and placebo controlled phase III study Randomized Phase III Study Comparing Etanercept, Cisplatin and Etoposide with Cisplatin and Etoposide in Patients with Extensive Stage and Chemotherapy Naïve |
| | Previously Treated Non-Small Cell Lung Cancer Patients. Principal Investigator (completed). 01H044, OSU 0036: A phase I feasibility study and a randomized double blinded and placebo controlled phase III study Randomized Phase III Study Comparing Etanercept, Cisplatin and Etoposide with Cisplatin and Etoposide in Patients with Extensive Stage and Chemotherapy Naïve Small-Cell Lung Cancer. Principal investigator (completed). 01H0102, OSU0041: A phase I/II Study of Etanercept and gemcitabine in Patients with Advanced Stage and Chemotherapy-Naïve Pancreatic |
| 2001 | Previously Treated Non-Small Cell Lung Cancer Patients. Principal Investigator (completed). 01H044, OSU 0036: A phase I feasibility study and a randomized double blinded and placebo controlled phase III study Randomized Phase III Study Comparing Etanercept, Cisplatin and Etoposide with Cisplatin and Etoposide in Patients with Extensive Stage and Chemotherapy Naïve Small-Cell Lung Cancer. Principal investigator (completed). 01H0102, OSU0041: A phase I/II Study of Etanercept and gemcitabine in Patients with Advanced Stage and Chemotherapy-Naïve Pancreatic Adenocarcinoma. Principal Investigator (completed, R21 funding). OSU-134: Phase I and Pharmaco-Biological Study of Thalidomide and Celecoxib as Modulators of Irinotecan's Anticancer Activity. Principal |

| 2002 | OSU 0120 A Phase II Study of Neoadjuvant rhuMAb VEGF (Bevacizumab) in Combination with Paclitaxel and Carboplatin in Surgically Resectable Non Small Cell Lung Cancer. Co-investigator (Completed, R21 funding) |
|------|---|
| 2003 | OSU 0238, CTEP 5889. A Pilot Study of Low dose Suramin as Modulator of Docetaxel and Gemcitabine in Patients with Previously Treated Non-Small Cell Lung Cancer (NSCLC). Principal investigator (completed) |
| 2003 | OSU 0250. A Phase 2, Randomized, Open-label Study of a Single Agent CI-1033 in Patients with Advanced Non-Small Cell Lung Cancer. Coinvestigator (completed) |
| 2003 | OSU-0317 A phase I dose escalation study of capecitabine, carboplatin and weekly paclitaxel and a Phase II trial of the combination in-patients with adenocarcinoma of unknown primary site. Co-Principal Investigator. (Completed) |
| 2003 | OSU-0248, A randomized, multicenter, open-label, Phase 2b Study of Velcade alone and Velcade plus irinotecan in patients with relapsed or refractory colorectal carcinoma. Institutional Principal Investigator. (completed) |
| 2004 | OSU-0330. A phase I dose escalation and biological study of capecitabine and mitomycin C (MMC) in-patients with gastrointestinal solid malignancies. Co-principal Investigator. (completed). |
| 2004 | OSU-356, A Phase II Study of Capecitabine and Docetaxel in Previously Untreated advanced Non-Small Cell Lung Cancer Patients. Co-Principal Investigator. (completed). R21 funding as Principal Investigator . |
| 2004 | OSU-0370, Phase 2 Study of KOS-862, Administered intravenously Weekly for 3 weeks every 4 weeks, in Patients with Non-Small Cell Lung Cancer who have Progressed following Initial Therapy for Advanced or Metastatic Disease. Institutional Principal Investigator. (completed). |
| 2004 | OSU-0421, A Randomized Phase II Study of Single Agent Erlotinib (Tarceva [™] , OSI-774) versus Standard Chemotherapy in Patients with Previously Untreated Advanced NSCLC and a Poor Performance Status. Institutional Principal Investigator (completed) |
| 2004 | OSU-0486, Phase 1 Dose Escalation Trial to Evaluate the Safety, Pharmacokinetics, and Pharmacodynamics of KOS-1584 in Patients with Advanced Solid Tumors. Principal Investigator (completed) |
| 2005 | OSU-0474, A Phase I, Open Label, Dose Escalation Study of Weekly Dosing with BB-10901 Followed by a Phase II Efficacy Expansion. Institutional Principal Investigator (completed) |

| 2005 | OSU-0443, A Phase II randomized study of OSI-774 in African American Patients with Advanced and Previously Treated Non-Small Cell Lung Cancer (NSCLC). Principal Investigator (completed) |
|------|---|
| 2005 | CALGB 60301 Phase I trial of BAY 43-9006 in pts w/ organ dysfunction. Institutional Principal Investigator (completed) |
| 2006 | CALGB 30406 A Phase II Randomized Study Of OSI-774 (Erlotinib) with or without carboplatin/paclitaxel in patients with previously untreated adenocarcinoma of the lung who never smoked, or were former light smokers. Institutional Principal Investigator (completed). |
| 2008 | OSU 08046, IRB 2008C0045, NCI CTEP 7003, A Phase II study of bortezomib (PS-341) for patients with advanced bronchiolo-alveolar carcinoma (BAC) or adenocarcinoma with BAC features. Institutional Principal Investigator (completed) |
| 2008 | OSU 07082, IRB2007C0087, Analysis of FANCD2 protein monoubiquitin status and nuclear foci formation in primary solid tumors. Principal Investigator . (active) |
| 2008 | OSU 08017, IRB2008C0079: A Pase II Study of Single Agent Sorafenib In Non-small cell lung cancer patients who never smoked or were former light smokers. Principal Investigator . (closed) |
| 2008 | OSU 7141, A Double-Blind, Randomized, Placebo-Controlled Phase III Study to Assess the Efficacy of recMAGE-A3 + AS15 Antigen-Specific Cancer Immunotherapeutic as Adjuvant Therapy in Patients with Resectable MAGE-A3-Positive Non-Small Cell Lung Cancer". Institutional Principal Investigator (closed) |
| 2009 | OSU 8145, Phase II Study of Intravenous Administration of Reovirus Serotype 3 - Dearing Strain (REOLYSIN®) in Combination With Paclitaxel and Carboplatin in Patients With Metastatic or Recurrent Non-Small Cell Lung Cancer Who Have KRAS or EGFR Activated Tumors. Oncolytics. Principal Investigator . (active). |
| 2009 | OSU 09023 An Open-label, Multicenter, Phase I/II Study of Pazopanib in Combination with Paclitaxel in First-line Treatment of Subjects with Stage IIIB wet/IV Non-small Cell Lung Cancer. Institutional Principal Investigator (completed) |
| 2009 | OSU 9100 (NCI 8472). ABT-888 as Monotherapy and in Combination with Mitomycin C in Patients with Solid Tumors with Deficiency in Homologous Recombination Repair. Principal Investigator (active) |
| 2011 | OSU 10152. Phase 1 Study of IMC-CS4, a Monoclonal Antibody Targeted to the CSF-1 Receptor (CSF-1R), in Subjects With Advanced Solid Tumors Refractory to Standard Therapy or for Which No Standard Therapy is Available. Institutional principal Investigator (active) |

Publications

Original Reports

- 1. Gautier Teofilo A., Imperato-McGinley Julianne, Bido Ramon A., **Villalona C. Miguel A.**, Alvarez A Francisco, Pichardo Marino. Incomplete Androgenic Insensitivity and 5 alpha reductase deficiency in the same family. Archivos Dominicanos de Pediatria, 22: 29-39, 1986
- 2. **Villalona-Calero Miguel A.**, Shrem Stanley S., Phelps Kenneth R., Case Report: Pneumomediastinum complicating Pneumocystis Carinii Pneumonia in a patient with AIDS. American Journal of Medical Sciences, 297(5): 328-330, 1989
- 3. **Villalona-Calero Miguel A.**, Ducker Thomas, Holasek Maureen, Kennedy B.J., Management of Testicular Seminoma Following Organ transplantation. <u>Medical and Pediatric Oncology</u>, 20:338-340, 1992.
- 4. Gonzales-Vela Jose, **Villalona-Calero Miguel A.**, Kennedy B.J., Extragonadal Germ Cell Tumors of the Abdomen. American Journal of Clinical Oncology, 15(4): 308-310, 1992
- 5. **Villalona-Calero M**, Eckardt J, Burris H, Kraynak M, Fields S, Bazan C, Lancanter J, Hander T, Goldblum R, Hammond L, Bari A, Drengler R, Rothenberg M, Hadovsky G, Von Hoff D. A phase I trial of human corticotropin-releasing factor (hCRF) in patients with peritumoral brain edema. <u>Annals of Oncology</u>, 9: 71-77, 1998.
- 6. Villalona-Calero M, Baker S D, Hammond L, Aylesworth C, Eckhardt G, Kraynak M, Fram R, Fischkoff S, Velagapudi R, Toppmeyer D, Razvillas B, Jakimowicz K, Von Hoff D.D, Rowinsky E. Phase I and Pharmacokinetic Study of the Water Soluble Dolastatin 15 Analog LU103793 in patients with advanced solid malignancies. <u>Journal of Clinical Oncology</u> 16(8): 2770-2779, 1998.
- 7. Rothenberg M, Sharma A, Weiss G, **Villalona-Calero M**, Eckardt J, Aylesworth C, Kraynak M, Rinaldi D, Rodriguez G, Burris H, Eckhardt G, Stephens C, Forral K, Nichol S, Von Hoff D. Phase I trial of Paclitaxel and Gemcitabine Administered Every-2-Weeks in Patients with Refractory Solid Tumors. <u>Annals of Oncology</u>, 9: 733-738,1998.
- 8. Rowinsky E, Smith L, Wang Y, Chaturvedi P, **Villalona M**, Campbell E, Aylesworth C, Eckhardt S, Hammond L, Kraynak M, Drengler R, Stephenson J, Harding M, Von Hoff D. Phase I and Pharmacokinetic Study of Paclitaxel in Combination with Biricodar, a Novel agent that Reverses Multidrug Resistance Conferred by overexpression of Both MDR1 and MRP. <u>Journal</u> of Clinical Oncology, 16 (9): 2964-2976, 1998
- 9. Drengler R, Kuhn J, Schaaf L, Rodriguez G, Villalona-Calero M, Hammond L, Stephenson J, Hodges S, Kraynak M, Station B, Elfring G, Locker P, Miller L, Von Hoff D, Rothenberg M. A Phase I and Pharmacokinetic Trial of Oral Irinotecan (CPT-11) administered daily x 5 every 3 weeks. Journal of Clinical Oncology, 17 (2): 685-696,1999
- 10. Diab SG, Baker S, Joshi A, Burris H, Cobb P, **Villalona-Calero M**, Eckhardt SG, Weiss G, Rodriguez G, Drengler R, Kraynak M, Hammond L, Finizio M, Von Hoff DD, Rowinsky E. A phase I and Pharmacokinetic study of losoxantrone and paclitaxel in patients with advanced solid tumors. <u>Clinical Cancer Research</u>, 5(2):299-308, 1999

- 11. Eckhardt S, Rizzo J, Sweeney K, Cropp G, Baker S, Kraynak M, Kuhn, **Villalona-Calero M**, Hammond L, Weiss G, Thurman A, Smith L, Drengler R, Eckardt J, Moczygemba J, Hannah A, Von Hoff D, Rowinsky E. A Phase I and Pharmacologic Study of the Tyrosine Kinase Inhibitor SU101 in Patients with Advanced Solid Tumors. <u>Journal of Clinical Oncology</u>, 14(4):1095-1104, 1999
- 12. **Villalona-Calero M**, Weiss G, Burris H, Kraynak M, Rodriguez G, Drengler R, Eckhardt G Reigner B, Moczygemba J, Ulrich Burger H, Griffin T, Von Hoff D, Rowinsky E. Phase I and pharmacokinetic study of the oral fluoropyrimidine capecitabine in combination with paclitaxel in patients with advanced solid malignancies. <u>Journal of Clinical Oncology</u>, 17(6):1915-1925, 1999
- 13. Britten C, Rowinsky E, Baker S, Agarwala S, Eckardt J, Barrington R, Diab S, Hammond L, Johnson T, **Villalona-Calero M**, Fraass U, Statkevich P, Von Hoff D, and Eckhardt SG. A phase I and pharmacokinetic study of temozolomide and cisplatin in patients with advanced solid malignancies. Clinical Cancer Research 5 (7): 1629-1637, 1999
- 14. **Villalona-Calero M**, Petit T, Kuhn J, Kraynak M, Smith L, Aylesworth C, Drengler R, Simmons C, Cobb P, Santabarbara P, Von Hoff D, Rowinsky E. Phase I and Pharmacokinetic Study of Crisnatol Mesylate on a Prolonged Infusion Schedule in Cancer Patients. <u>Clinical Cancer Research</u> 5 (11):3369-3378, 1999
- 15. **Villalona-Calero M***, Hidalgo M*, Eckhardt SG, Drengler R, Rodriguez G, Hammond L, Diab S, Weiss G, Garner A, Campbell E, Davidson K, Louie A, O'Neil J, R. Diasio, Von Hoff D, Rowinsky E. A phase I and Pharmacologic Study of PN401 and 5-Fluorouracil in Patients with Advanced Solid Malignancies. <u>Journal of Clinical Oncology</u> 18(1): 167-177, 2000 *This paper has two first authors, both contributed equally to this paper
- 16. Eckhardt SG, Baker SD, Britten CD, Hidalgo M, Siu L, Hammond L, Villalona-Calero MA, Felton S, Drengler R, Kuhn JG, Smith SL, MacDonald J, Moczygemba J, Weitman S, Von Hoff DD, Rowinsky EK. A Phase I and Pharmacokinetic Study of MGI 114, a Novel Mushroom-derived Cytotoxin Administered for Five Consecutive Days Every Four Weeks. <u>Journal of Clinical Oncology</u>. 18(24): 4086-4097, 2000
- 17. **Villalona-Calero M**, Eder JP, Toppmeyer D, Allen LF, Velagapudi R, Myers M, Amato A, Kagen-Hallet K, Razvillas B, O'Connor L, Kufe D, Von Hoff D, and Rowinsky E. A phase I and pharmacokinetic (PK) study of LU79553, a novel bis-naphthalamide, on a daily x 5 schedule in patients with advanced solid tumors. <u>Journal of Clinical Oncology</u>. 19(3): 857-869, 2001
- 18. Rothenberg M, Kuhn J, Schaaf L, Rodriguez G, Eckhardt SG, Villalona-Calero M, Rinaldi D, Hammond L, Hodges S, Sharma A, Elfring G, Petit R, Miller L, Von Hoff D. A Phase I and Pharmacokinetic Trial of Irinotecan (CPT-11) Administered Every Two Weeks. <u>Annals of Oncology</u> 12: 1631-1641, 2001.
- 19. **Villalona-Calero M**, Blum J, Jones S, Diab S, Elledge R, Khoury P, Von Hoff D, Kraynak M, Moczygemba J, Kromelis P, Griffin T, Rowinsky E. A Phase I study and Pharmacologic Study of Capecitabine and Paclitaxel in Advanced Breast Cancer. <u>Annals of Oncology</u> 12(5): 605-614, 2001.
- 20. Zhu W, Dai Z, Ding H, Srinivasant K, Hall J, Duan W, **Villalona-Calero M**, Plass C, Otterson G. Increased expression of unmethylated CDKN2D gene by 5-aza 2'deoxycytidine in human lung cancer cells. Oncogene 20: 7787-7796, 2001

- 21. **Villalona-Calero M**, Eckhardt SG, Weiss G, Campbell E, Hidalgo M, Kraynak M, Beijnen J, Jimeno J, Von Hoff D, Rowinsky E. A Phase I And Pharmacokinetic Study of ET-743, a Novel DNA Minor Groove Binder of Marine Origin Administered as a 1-hour infusion daily x 5 Days. Clinical Cancer Research 8: 75-85, 2002.
- 22. Duan Wenrui, Ding H, Zhu W, Otterson G, **Villalona-Calero M.** Detection of transgene and host endogenous homologous gene expression and silencing using RT-PCR-Heteroduplex technique in transgenic animal models. Biotechniques 33: 58-66, 2002.
- 23. Rudin C, Otterson G, Mauer A, **Villalona-Calero M**, George C, Prange B, Tomek R, Vokes E. A pilot trial of G3139, a bcl-2 antisense oligonucleotide, with paclitaxel in patients with chemorefractory small cell lung cancer. Annals of Oncology 13:539-45, 2002.
- 24. Nadella P, Shapiro C, Otterson G, Hauger M, Erdal S, Kraut E, Clinton S, Shah M, Stanek M, Monk P, **Villalona-Calero M.** Pharmaco-biologically based scheduling of capecitabine and docetaxel results in antitumor activity in resistant human malignancies. <u>Journal of Clinical Oncology</u> 20: 2616-2623, 2002.
- 25. Patnaik A, Rowinsky E K, **Villalona M A**, Hammond L A, Britten C D, Siu L, Goetz A, Felton S, Burton S, Valone F, Eckhardt S. G. A phase I study of pivaloyloxymethyl butyrate, a prodrug of the differentiating agent butyric acid, in patients with advanced solid malignancies. <u>Clinical Cancer Research 8</u>: 2142-2148, 2002.
- 26. **Villalona-Calero M**, Kolesar J. Mitomycin C as a Modulator of Irinotecan Anticancer Activity. Oncology 16: 8, supp 7: 21-25, 2002
- 27. Duan W, Ding H, Subler M, Zhu W, Zhang H, Stoner G, Windle J, Otterson G, Villalona-Calero M. Lung specific expression of mutant p53 (273H) results in high frequency of lung adenocarcinoma in transgenic mice. Oncogene 21: 7831-7838, 2002.
- 28. Zhu W, Srinivasan K, Dai Z, Ding H, Duan W, Yee L, **Villalona-Calero M,** Plass C, Otterson G. Hypermethylation induced decrease in Sp1/Sp3 binding is associated with reduced p21^{Cip1} expression in response to depsipeptide treatment. <u>Molecular and Cellular Biology</u>. 23(12):4056-4065, 2003. PMCID:PMC 156121
- 29. **Villalona-Calero M,** Guill Wientjes, Gregory A Otterson, Steven Kanter, Donn Young, Anthony Murgo, Beth Fischer, Carrie DeHoff, Danny Chen, Teng Kuang Yeh, SaeHeum Song, Michael Grever, Jessie L Au. Phase I Study of Low Dose Suramin as a Chemosensitizer in Patients with Advanced Non-Small Cell Lung Cancer. <u>Clinical Cancer Research.</u> 9(9):3303-11, 2003.
- 30. Ding H, Duan W, Zhu W, Ju R, Srinivasan K, Otterson G, **Villalona-Calero M.** Mechanisms of p21^{WAF1/Cip1} Response to DNA Damage Induced by the Topoisomerase II Inhibitors Genistein and Etoposide in Human Lung Cancer Cells. <u>Biochemical and Biophysical Research</u> Communications. 13;305(4):950-6, 2003.
- 31. Venook A, Enders Klein C, Fleming G, Hollis D, Leichman CG, Hohl R, Byrd J, Budman D, Villalona, M, Marshall J, Rosner G, Ramirez J, Kastrissios H, Ratain M. A Phase I and Pharmacokinetic Study of Irinotecan in Patients with hepatic or Renal Dysfunction or with prior pelvic Radiation: CALGB 9863. Annals of Oncology. 14: 1783-1790, 2003

- 32. Zhu W, Hileman T, Ke Y, Wang P, Duan W, Dai Z, Tong T, **Villalona-Calero**, M, Plass C, Otterson G. 5-aza-2'-deoxycytidine activates p53/p21^{waf1/cip1} pathway to inhibit cell proliferation. The Journal of Biological Chemistry 279(15):15161-6, 2004
- 33. Duan W, Gao L, Druhan L, Zhu W, Otterson G, and Villalona-Calero M. Pirh2, a newly identified ubiquitin protein ligase, expression in lung cancer. <u>Journal of The National Cancer Institute</u>. 96 (22): 1718-1721, 2004.
- 34. Winegarden J, Mauer A, Otterson G, Rudin C, **Villalona-Calero M,** Lanzotti V, Szeto L, Kasza K, Hoffman P, Vokes E. A Phase II study of oxaliplatin and paclitaxel in patients with advanced non-small cell lung cancer. <u>Annals of Oncology</u>. 15(6):915-20, 2004.
- 35. **Villalona-Calero M**, Ritch P, Figueroa J, Otterson G, Belt R, Dow E, George S, Leonardo J, McCachren S, Miller GL, Modiano M, Valdivieso M, Holmlund J. A Phase I/II Study of ISIS 3521, an Antisense Inhibitor of Protein Kinase C Alpha, in Combination with Cisplatin and Gemcitabine in Patients with Advanced Non Small Cell Lung Cancer. <u>Clinical Cancer Research</u>. 10(8):6086-93, 2004
- 36. Kindwall-Keller T, Otterson G, Young D, Neki A, Criswell T, Nuovo G, Soong R, Diasio R, Villalona-Calero, M.A. Phase II evaluation of docetaxel-modulated capecitabine in previously treated patients with non-small cell lung cancer. Clinical Cancer Research 11:1870-1876, 2005
- 37. Weber F, Fukino K, Sawada T, Williams N, Sweet K, Brena R, Plass C, Caldes T, Mutter G, Villalona-Calero M*, Eng C. Variability in organ-specific EGFR mutational spectra in tumor epithelium and stroma may be the biological basis for differential responses to tyrosine kinase inhibitors. British Journal of Cancer 2005 May 23;92(10):1922-6. *Co-corresponding author. PMC 2361765
- 38. Otterson, G.A., Lavelle, **Villalona-Calero, M.A**, Shah, M, Wei, X., Chan, K, Fischer, B, Zweibel, J, Grever, M. A Phase I Clinical and Pharmacokinetic Study of Fenretinide Combined with Paclitaxel and Cisplatin for Refractory Solid Tumors. <u>Investigational New Drugs</u> 2005 23(6):555-62
- 39. Mita A, Sweeney C, Baker S, Goetz A, Felton S, Hammond L, Patnaik A, Tolcher A, Villalona-Calero M, Sandler A, Chaudhuri T, Molpus K, Latz J, Johnson R, Rowinsky E, Takimoto C. A phase I and pharmacokinetic study of pemetrexed administered intravenously every 3 weeks to advanced cancer patients with impaired renal function. <u>Journal of Clinical Oncology</u>. January 2006 24(4):552-62
- 40. Monk JP, Phillips G, Waite Ross, Kuhn J, Schaaf L, Otterson G, Rhoades C, Shah M, Criswell T, Caligiuri M, **Villalona-Calero M**. Tumor necrosis factor alpha blockade improves tolerability of dose intensive chemotherapy. <u>Journal of Clinical Oncology</u>. April 2006 24(12):1852-9.
- 41. Chen D, Song S, Wientjes M.G, Yeh T, Zhao L, **Villalona-Calero M**, Otterson G, Jensen R, Grever M, Murgo A, and Au J. Non toxic suramin as a chemosensitizer in patients: Dosing nomogram development. Pharmaceutical Research 2006 Jun;23(6):1265-74
- 42. **Villalona-Calero M.A**, Schaaf L, Otterson G, Panico K, Duan W, Kleiber B, Shah M, Young D, Phillips G, Wu W, Kuhn J. Pharmaco-biological study of thalidomide and celecoxib as potential modulators of irinotecan's activity in cancer patients. <u>Cancer Chemotherapy and Pharmacology</u>. 2007; 59(1):23-33.

- 43. Duan W, Villalona-Calero MA . RCHY1 (ring finger and CHY zinc finger domain containing 1). https://atlasgeneticsoncology.org//Genes/RCHY1ID43012ch04q21.html
- 44. Mrozek E, Ramaswamy B, Young D, Rhoades C, Kendra K, Allen J, Hauger M, Watson H, Moore T, Merrimen N, Nadella P, **Villalona-Calero M**, and Shapiro C. Phase II study of weekly docetaxel and capecitabine in metastatic breast cancer patients. <u>Clinical Breast Cancer</u> 2006;7(2):141-5.
- 45. Duan W, Gao L, Wu X, Zhang Y, Otterson G, **Villalona-Calero M**. Differential response between the p53 ubiquitin-protein ligases Pirh2 and Mdm2 following DNA damage in human cancer cells. Experimental Cell Research 2006; 312(17):3370-8.
- 46. Ross P, Grecula J, Bekaii-Saab T, **Villalona-Calero M,** Otterson G, Magro C. Incorporation of photodynamic therapy as an induction modality in non-small cell lung cancer. <u>Laser in Surgery and Medicine</u>. 2006; 38(10):881-9
- 47. Otterson G, Villalona-Calero M, White D, Sharma S, Kris M, Gerber M, Imondi A, Ratain M, Schiller J, Sandler A, Kraut M, Mani S, Murren J. Results from a phase I study of inhaled doxorubicin for patients with metastatic tumors to the lungs. <u>Clinical Cancer Research</u>. 15;13(4):1246-52, 2007
- 48. Bekaii-Saab T, Williams N, Plass C, **Villalona-Calero M**, Eng C. A novel mutation in the tyrosine kinase domain of ERBB2 in hepatocellular carcinoma. <u>BMC-Cancer</u>. 2006 Dec 6;6(1):278
- 49. Duan W, Villalona-Calero MA . MDM2 (transformed mouse 3T3 cell double minute 2, p53 binding protein). Atlas Genet Cytogenet Oncol Haematol. December 2006. URL: http://AtlasGeneticsOncology.org/Genes/MDM2ID115ch12q15.html
- 50. Miller A, Murry D, Owzar K, Hollis D, Lewis L, Kindler H, Marshall J, **Villalona-Calero M**, Edelman M, Hohl R, Lichtman S, and Ratain M. Phase I and Pharmacokinetic Study of Erlotinib for Solid Tumors in Patients with Hepatic or Renal Dysfunction: Cancer and Leukemia Group B Study 60101. J Clin Oncol. 25(21):3055-60, 2007.
- 51. Duan W, Gao L, Jin D, Otterson GA, **Villalona-Calero MA**. Lung specific expression of a human mutant p53 affects cell proliferation in transgenic mice. <u>Transgenic Research</u> 17(3):355-66, 2008.
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- 1. Vaickus Louis, **Villalona-Calero Miguel A.**, Caligiuri Therese, Acute Progranulocytic Leukemia (APL): Possible In Vivo Differentiation by Granulocyte-Colony Stimulating Factor (G-CSF). Leukemia, 7(10): 1680-81, 1993
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Invited Editor Reviewed Articles:

- 1. Rivas-Perez H, Villalona, M. Rehabilitatcion Pulmonar para Pacientes con Cancer del Pulmon. Neumos, 23 (1), 2014: 22-25
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- 165. Duan W, Gao L, Brooks C, Kalvala A, Wu X, Otterson G, **Villalona-Calero MA**. Establishment of P53 mutant type specific spontaneous lung tumor in transgenic mice for treatment. Proceedings of the 2012 AACR Annual Meeting, abstr 4740
- 166. Kummar S, Oza A, Fleming G, Sullivan D, Gandara D, Erlichman C, Villalona-Calero M, Morgan R, Chen A, Ji J, Allen D, Lih C, Steinberg S, Williams P, Conley B, Doroshow J. Randomized trial of oral cyclophosphamide (C) with or without veliparib (V), an oral poly (ADP-ribose) polymerase (PARP) inhibitor, in patients with recurrent BRCA-positive ovarian, or primary peritoneal or high-grade serous ovarian carcinoma. Proceedings of the 2012 ASCO Annual Meeting, June 2012, Abstr. 5020.
- 167. **Villalona-Calero M,** Lam E, Otterson G, Zhao J, Timmons M, Subramaniam D, Hade E, Gill G, Coffey M, Bertino E. Phase II Trial of Oncolytic Reovirus in Combination with Chemotherapy in NSCLC Pts with Kras Activated Tumors. Proceedings of the 24th EORTC-NCI-AACR Symposium on Molecular Target and Cancer Therapeutics, European Journal of Cancer, Volume 48, Suppl. 6, November 2012, abstr. 603.
- 168. Villalona-Calero M, Duan W, Zhao W, Shilo K, Ji J, Thurmond J, Norris A, Rose J, Layman R, Marshall J, Bekaii-Saab T, Chen A. Phase I trial of veliparib or mitomycin (MMC) + veliparib in patients with sporadic solid tumors screened for somatic deficiency in the Fanconi Anemia (FA) pathway. Proceedings of the 2013 AACR Annual Meeting, abstr 4740. Abstr Late Breaking 139.
- 169. Singh M, Leasure J, Chronowski C, Li N, Bondra K, Duan W, **Villalona M**, Vergis A, Hensley L, Kaplon R, Geier B, Kurmasheva R, Woods G, Hammond S, Houghton P, Pelloski C. Targeting FANCD2 as a radiosensitizer in pediatric rhabdomyosarcoma. Proceedings of the 2013 AACR Annual Meeting, abstr 4439.
- 170. Kalvala A, Gao L, Barnwel B, Otterson G, **Villalona Calero M**, Duan W. Mutations in Rad51C in colon tumors. Proceedings of the 2013 AACR Annual Meeting, abstr 4221.
- 171. Gao L, Duan W, Barnwell B, Kalvala A, Otterson G, **Villalona-Calero M**. Sensitivity of small cell lung cancer cells with defective Fanconi Anemia (FA) pathway to BCL2 inhibitors. Proceedings of the 2013 AACR Annual Meeting, abstr 4365.
- 172. Duan W, Rees T, Vu K, Barnwell B, Gao L, Kalvala A, Wu X, Otterson G, **Villalona-**Calero **M.** Promoter hypermethylation and gene expression of FANCF in non-small cell lung cancer (NSCLC). Proceedings of the 2013 AACR Annual Meeting, abstr 4246.
- 173. Stinchcombe T, Sholl L, Wang X, Gu L, Socinski M, Rodig S, Capelletti M, Crawford J, Edelman M., **Villalona-Calero M**, Kratzke R, Vokes E, Miller V, Janne P. An analysis of the prevalence of *HER2* and *KRAS* mutations, and ALK rearrangements and clinical outcomes in Cancer and Leukemia Group B [CALGB (Alliance)] trial 30406 in advanced non-small cell lung cancer

- (NSCLC). 2013 ASCO Annual Meeting Proceedings Errata. J Clin Oncol 31, 2013 (suppl; abstr 8039)
- 174. Ramaswamy B, Zhang J, Hall N, Schregel K, Lustberg M, Wesolowski R, Mrozek E, Layman R, Olson E, Ottman S, Camp A, Chalmers J, Geyer S, **Villalona-Calero M**, Shapiro C, Grever M, Knopp M. NCI 8609: Interim fluoro-3'-deoxythymidine (FLT) PET imaging findings from the phase I trial of PARP inhibitor veliparib (V) and carboplatin (C) in advanced breast cancer. 2013 ASCO Annual Meeting Proceedings. J Clin Oncol 31, 2013 (suppl; abstr 1023)
- 175. **Villalona-Calero M**, Lam E, Zhao W, Otterson G, Subramaniam D, Chao B, Timmons M, Schaaf L, M Gill G, Coffey M. Phase II Trial of Oncolytic Reovirus in Combination with Chemotherapy in NSCLC Pts with Kras Activated Tumors. 15th World conference in lung cancer. P1.11-026, 2013
- 176. Duan W, Gao L, Kalvala A, Brooks C, Barnwell B, Mo X, Ding H, Shilo K, Otterson G, and **Villalona-Calero M**. Type of P53 mutation influences oncogenic potential and spectrum of associated K-ras mutations in lung specific transgenic mice. 15th World conference in lung cancer, 2013.
- 177. Chen W, Brodsky S, Zhao W, Otterson G, Villalona-Calero M, Satoskar A, Hasan A, Pelletier R, Ivanov I, Ross P, Nadasdy T and Shilo K. Y-Chromosome Status Identification Suggests a Recipient Origin of Post-Transplant Non-Small Cell Lung Carcinomas: Chromogenic in situ Hybridization Analysis. United States College of Pathology meeting. San Diego. 2014
- 178. Kalvala A, Gao L, Barnwell B, Otterson G, **Villalona-Calero M**, and Wenrui Duan. Identification of a Novel Rad51c-ATXN7 fusion gene in colorectal tumors. 2014 AACR Annual Meeting, p2407
- 179. Gao L, Barnwell B, Kalvala A, Otterson G, Duan W and **Villalona-Calero M**. Combined BCL-2/XL and mTor Inhibition Promotes Apoptosis in Small Cell Lung Cancer. 2014 AACR Annual Meeting, p5434.
- 180. J. C. Grecula, S. Elias, K. Thelen, M. Knopp, G. Otterson, P. Ross, E. Kassis, M. Welliver, M. Villalona-Calero, K. Shilo, S. Lo, G. Jia, W. C. Yu, B. Yuh, S. Ghosh, E. Bertino, N. Mayr. Dynamic-Contrast Enhanced MR and Volume Regression rate as a preoperative predictive assay in patients with Non Small Cell Lung Cancer, 2014 ASTRO meeting.
- 181. Bertino E, McMichael E, **Villalona-Calero M**, Grever M, Carson W, Otterson G. Enhancement of cetuximab-induced antibody-dependent cellular cytotoxicity (ADCC) with lenalidomide in advanced solid tumors: A phase 1 trial. 2014 ASCO annual meeting. J Clin Oncol 32:5s, 2014 (suppl; abstr 3044).
- 182. Wesolowski R, Zhao M, Geyer S, Lustberg M, Mrozek E, Layman R, Macrae E, Zhang J, Hall N, Schregel K, Ottman S, Camp A, Chalmers J, Andreopoulou E, **Villalona-Calero M**, Shapiro C, Knopp M, Grever M, Ramaswamy B. Phase I trial of the PARP inhibitor veliparib (V) in combination with carboplatin (C) in metastatic breast cancer (MBC). 2014 ASCO annual meeting. J Clin Oncol 32:5s, 2014 (suppl; abstr 1074)
- 183. Camidge D, Ou S, Shapiro G, Otterson G, Villaruz L, **Villalona-Calero M**, Iafrate A, Varella-Garcia M, Dacic S, Cardarella S, Zhao W, Tye L, Stephenson P, Wilner K, James L, Socinski M. 2014 ASCO annual meeting. J Clin Oncol 32:5s, 2014 (suppl; abstr 8001)

184. Monk P, Liu G, Stadler W, Geyer S, Sexton J, Wright J, Villalona-Calero M, Wade J, Szmulewitz R, Gupta S, Mortazavi A, Dreicer R, Pili R, Cooney M, Dawson N, George S, Garcia J. Phase II randomized, double-blind, placebo-controlled study of tivantinib in men with asymptomatic or minimally symptomatic metastatic castrate resistant prostate cancer (mCRPC). ASCO GU Symposium 2015.

Oral Presentations in National/International Meetings

- Oncolytic reovirus in combination with paclitaxel/carboplatin in NSCLC patients with RAS activated malignancies, long-term results. 16th World Conference on Lung Cancer. Denver Colorado September 2015.
- 2. Veliparib Alone or in Combination with Mitomycin C in Patients with Solid Tumors with Functional Deficiency in Homologous Recombination Repair. Cancer Therapy and Evaluation Program annual meeting. Bethesda, Maryland. October 2014.
- 3. University of Alabama, Birgminham Grand Rounds. "DNA repair as an anticancer target" May 2014.
- 4. Karmanos Cancer Center, Detroit Michigan Grand Rounds. "DNA repair as an anticancer target" April 2014.
- 5. Phase I trial of veliparib or mitomycin (MMC) + veliparib in patients with sporadic solid tumors screened for somatic deficiency in the Fanconi Anemia (FA) pathway. Minisimposium, American Association of Cancer Research 2013 meeting, Washington DC, April 2013.
- 6. Invited Speaker. "The latino population and cancer, challenges for the health care provider." Oncology Nursing Society, Columbus, Ohio, October 10, 2012.
- 7. The Ohio State University, Department of Pathology Grand Rounds. "Molecular targeted agents in solid tumor oncology". Nov 8, 2011
- 8. Roswell Park Cancer Institute Grand Rounds. "Challenging Targets in Solid Tumor Oncology" Oct 28, 2011.
- 9. The Ohio State University, Dept of Internal Medicine Grand Rounds. "Molecular targeted agents in solid tumor oncology; a new era for the practicing clinician". Sept 1, 2011.
- 10. Key note address. CEDIMAT chemotherapy unit inauguration. "The Evolution of Cancer Treatment". Santo Domingo Dominican Republic, August 25, 2011.
- 11. Invited Speaker. "Cáncer del Pulmón: Patogenia y Estadiaje." Society Congress. Congreso Neumología República Dominicana. Santo Domingo, Dominican Republic. May 2011.
- 12. Invited Speaker. "Logros en la Personalización del Tratamiento del Cáncer Pulmonar." Society Congress. Congreso Neumología República Dominicana. Santo Domingo, Dominican Republic. May 2011.
- 13. Invited Speaker Co-Chair. "Can Advancing our Understanding of the Human Genome Reduce Breast Cancer Health Disparities?" MICR Scientific Symposium. Proceeding of AACR 102nd Annual Meeting. Orlando, FL April 2011.
- 14. Invited Speaker. "Phase I trial of veliparib or Mitomycin C + veliparib in solid tumor patients with Fanconi DNA repair defects." Spring 2011 CTEP Early Drug Development Meeting Washington NCI. Bethesda, MD. March 2011.
- 15. Invited Speaker. "Challenging Targets in Solid Tumor Oncology." Grand Rounds, Cleveland Clinic. Cleveland, OH. March 2011.
- 16. Invited Speaker. "Lung Cancer: New Diagnostic and Treatment Options." 2011 Puerto Rico Chapter Scientific Meeting American College of Physicians. San Juan, Puerto Rico. February 2011.
- 17. Invited Speaker. "Difficult Cancer Targets." Department of Pharmacology Seminar/Journal Club. Ohio State University. Columbus, OH. November 2010.
- 18. Invited Speaker. "Difficult Cancer Targets in Lung Cancer." Lung Cancer Conference 2010. Ohio State University, Columbus, OH. November 2010.
- 19. Invited Speaker. "A Latino in the Heart of it all." 2nd Annual Ohio Latino Cancer Summit, Glenwood United Methodist Church, Columbus, OH. September 2010.

- 20. Invited Speaker. "Modulation of Anticancer Agents in the Clinic". Grand Rounds, Virginia Commonwealth University Massey Cancer Center, Richmond, Virginia. October 2009.
- 21. Invited Speaker. "Science in lung cancer: Where are we, and where are we going?" Jornada UCE-Universidad Central del Este, Santo Domingo, Dominican Republic. October 2009.
- 22. Invited Speaker. "Comprehensive management of early stage lung cancer". Jornada UCE-Universidad Central del Este, Santo Domingo, Dominican Republic. October 2009.
- 23. Key Note Speaker. Conferencia Magistral del Egresado, Dr Manuel Felipe Pimentel Imbert: "Lung Cancer in the non-smoker, Molecular Biology Clinically Applied". Universidad Nacional Pedro Henriquez Urena Medical School, Santo Domingo, Dominican Republic. April 2009.
- 24. Speaker and Co-Chair. The Molecular Biology of Lung Cancer in Never Smokers: a Different Disease. New Concepts in Organ Site Research, American Association for Cancer Research, Denver, Colorado. April 2009.
- 25. Discussant and Chairperson. Clinical Trials 3, Mini-symposium. American Association for Cancer Research, Denver, Colorado. April 2009.
- 26. Chair-person and Moderator. Cancer Drug Development as a Successful Public-Private Enterprise: The NCI in Partnership with Industry. Science Policy Forum. American Association for Cancer Research, Denver, Colorado. April 2009.
- 27. Invited Speaker. Epidemiologia, patologia y manejo del cancer de pulmon, enfermedad Temprana. Jornada del Cancer del pulmon. Universidad Central del Este, San Pedro de Macoris, Dominican Republic. November 2008
- 28. Invited Speaker. Manejo del cancer de pulmon, enfermedad avanzada. Jornada del Cancer del pulmon. Universidad Central del Este, San Pedro de Macoris, Dominican Republic. November 2008
- 29. Key Note Speaker. El mosquito y el coronel. Jornada del Cancer del pulmon. Universidad Centrals del Este, San Pedro de Macoris, Dominican Republic. November 2008
- 30. Invited Speaker. Modulation of Anticancer Agents in the Clinic: Challenges and opportunities. Grand Rounds, Simon Cancer Center Indiana/Purdue University, Indianapolis, Indiana. August 2008,
- 31. Invited Speaker. Modulation of Anticancer Agents in the Clinic: Challenges and opportunities. American Association for Cancer Research Centennial Conference in Translational Research, Monterrey California. July 2008
- 32. Invited Speaker. Tyrosine Kinase Inhibitors in Lung Cancer. Special Grand Rounds, Pennsylvania State University. June 2008
- 33. Invited Speaker. Treatment of Lung Cancer. Annual Meeting of the Dominican Society of Hematology and Oncology, Punta Cana, Dominican Republic. April 2008
- 34. Invited Speaker. Predictive Factors of Response to EGFR Tyrosine Kinase Inhibitors. Cancer Center Grand Rounds, The Ohio State University Columbus, OH. February 2008
- 35. Invited Speaker. EGFR Tyrosine Kinase Inhibitors in Lung Cancer. Special Grand Rounds, Mayo Clinic Jacksonville. January 2008
- 36. Invited Speaker, Predictive Factors of Response to EGFR Tyrosine Kinase Inhibitors. Grand Rounds UAB Birmingham, Alabama. October 2007
- 37. Invited Speaker, Epidermal Growth Factor Receptor Tyrosine Kinase Inhibitors in Lung Cancer: Clinical and Molecular Predictors of Response. Grand Rounds Barbara Ann Karmanos Cancer Institute. Detroit, Michigan. April 2007
- 38. Invited Speaker, Epidermal Growth Factor Receptor Inhibitors in Lung Cancer; Clinical and Molecular Predictors of Activity. Pharmacology and Drug Discovery/Development in the Era of Genomics Symposium. Columbus, Ohio. March 2007
- 39. Invited Speaker, Predictive Factors of Response to EGFR Inhibitors. 21st century Care for Lung Cancer Symposium, Columbus Ohio. March 2007

- 40. Invited Speaker, Prognostic and Predictive Factors in Colorectal Cancer. The 2nd Messina Conference in Cancer Pharmacogenomics. Sicily, Italy. January 2007
- 41. Invited Speaker, "TNF in cancer, friend or foe?" Human Biology Grand Rounds, Fred Hutchinson Cancer Research Center, Seattle, Washington. October 2006
- 42. Invited Speaker, "Non small cell lung cancer: Advances in treatment". Southeast Chapter of Oncology Nurses Society, Fall Conference, Ohio University, Zanesville Campus Center, Zanesville, Ohio. September, 2006
- 43. Invited Speaker, "Latinos in the U.S.: Cultural sensitivity issues and their impact in health care." Key note speaker, Ohio University, Athens, Ohio. June, 2006
- 44. Platform Presentation. "First-In-Human Phase I trial of a Novel Epothilone, KOS-1584." American Society of Clinical Oncology, 42nd Annual Meeting, Atlanta, GA, June, 2006
- 45. Keynote Speaker, "Tyrosine kinase inhibitors in lung cancer therapy." Novel Therapies in Thoracic Oncology Symposium, University of Minnesota Medical School. July, 2005
- 46. Invited Speaker, "Advances in the treatment of non-small cell lung cancer." Sylvester Comprehensive Cancer Center, Grand Rounds, University of Miami, Florida. December 2004
- 47. Invited Speaker, "Cachexia in pancreatic cancer molecular mechanisms and potential practical approaches". Advances in the multidisciplinary management of pancreatic disease Symposium, The Ohio State University Comprehensive Cancer Center and Department of Surgery, Columbus Ohio. September 2004
- 48. Plenary Presentation. "Variable responses to EGFR tyrosine kinase inhibitors in non-small cell lung cancer (NSCLC) may be due to variable somatic EGFR mutational spectra.", The third international Chicago Symposium on malignancies of the Chest and Head and Neck. October 2004
- 49. Invited Speaker, "The Hispanic/Latino patients, cultural implications in health care." The Susan G. Komen Breast Cancer Foundation, Columbus, Ohio. January 2004
- 50. Invited Speaker, "Chemotherapy for thoracic malignancies." The Ohio State University Continuing Medical Education Webcast for the 21st century, Columbus, Ohio. January 2004
- 51. Invited Speaker. "Modulation of chemotherapy agents at the molecular level: A potentially beneficial strategy in advanced thoracic malignancies." Rushing against thoracic malignancies conference, The Ohio State University, Columbus, Ohio. September, 2003
- 52. Invited Speaker, "New therapies for colon cancer." School of Pharmacy, University of Wisconsin, Twenty-Fourth Annual Madison Clinical Conference, Advances and Controversies in Oncology Pharmacotherapy. Madison, Wisconsin. March, 2003
- 53. Invited Speaker, "Tumor Necrosis Factor In Cancer, Friend or Foe?" Department of Interdisciplinary Oncology Grand Rounds, Lee Moffit Cancer Center, Tampa Florida. July 2002
- 54. Invited Speaker, "TNF blockade as an adjunct to cancer therapy." Internal Medicine Grand Rounds, The Ohio State University, Columbus, Ohio. July 2002
- 55. Invited Speaker, Newer schedules with Capecitabine/Docetaxel." Satellite Symposium, Miami Breast Cancer Conference, Miami, Florida. March, 2002
- 56. Invited Speaker, "Newer schedules with Capecitabine/Docetaxel." Satellite Symposium, San Antonio Breast Cancer Conference, San Antonio, Texas. December 2001
- 57. Invited Speaker, "TNF receptor blockade in cancer therapy." University of Arizona Cancer Center Grand Rounds, Tucson Arizona. October, 2001
- 58. Invited Speaker, "TNF receptor antibodies for management of cancer associated fatigue/cachexia." Congress on Monoclonal Antibodies in Cancer, Alberta, Canada. September 2001

- 59. Invited Presentation. "Phase I study of Suramin/Paclitaxel carboplatin in patients with advanced non-small cell lung cancer." Cancer Therapy and Evaluation Program Drug Development meeting, National Cancer Institute, Bethesda MA. September 2001
- 60. Invited Speaker, "A novel strategy to revert Paclitaxel resistance in patients with non-small cell lung cancer." Cancer and Leukemia Group B, Fall meeting, Amelia Island Plantation, Jacksonville Florida. September 2001
- 61. Invited Speaker, "Pharmacologically based Phase I study of Irinotecan and mitomycin-C in patients with solid malignancies." The University of Texas, M.D. Anderson Cancer Center Investigators' Workshop, Colorado Springs, Colorado. July, 2001
- 62. Invited Speaker, "Highlights of the 2001 ASCO meeting: Colorectal Cancer". , The Columbus Community Clinical Oncology Program, Columbus, Ohio. June, 2001
- 63. Keynote speaker, "Progress and opportunity in cancer research". Ohio University, Zanesville Campus, Ohio. March 2001
- 64. Invited Speaker, "Exploiting pharmacologic interactions of anticancer drugs at the molecular level." Medical Oncology Grand Rounds, University of Minnesota. February 2001
- 65. Invited Speaker, "Treatment of non-small cell lung cancer: The present and the future." Medical Oncology Grand Rounds, University of Cincinnati, Cincinnati, Ohio. February, 2000
- 66. Guest Professor, "New Drugs in the treatment of stomach cancer." XIII Oncology Centroamerican and Caribbean Congress and Integrated Congresses, Tegucigalpa, Honduras. November 2000
- 67. Guest Professor, "New Drugs in the treatment of colorectal cancer" XIII Oncology Centroamerican and Caribbean Congress and Integrated Congresses. Tegucigalpa, Honduras. November 2000
- 68. Invited Speaker. "Capecitabine and the taxanes: Synergy or speculation?" Stanley S. Scott Oncology Grand Rounds, Louisiana State University Medical Center, New Orleans, Louisiana. August 2000
- 69. Invited Speaker, "Capecitabine in the treatment of breast cancer." Grand Rounds, University of Tennessee at Knoxville, Knoxville, Tennessee. 1999
- 70. Platform Presentation, "Phase I and parmacokinetic (Pk) study of Lu79553, a novel bisnaphthalamide on a daily X 5 schedule." American Society of Clinical Oncology Annual Meeting, Los Angeles, California. May 1998
- 71. Plenary Presentation, "Paclitaxel and Capecitabine: A synergistic combination?" Chemotherapy Foundation Symposium XVI Innovative Cancer Therapy for Tomorrow, New York, New York. November 1998
- 72. Invited Speaker, "The discovery of New Drugs for the Treatment of Cancer: The Process; What is New?" VI Jornadas del Interior, Cordoba, Argentina. 1998
- 73. Invited Speaker, "Non Small Cell Lung Cancer: Where are we? Where are we going?" VI Jornadas del Interior, Cordoba, Argentina. 1998
- 74. Invited Speaker, Treatment of advanced lung cancer. Guest Professor. XII Oncology Centroamerican and Caribbean Congress and Integrated Congresses. Antigua, Guatemala. October 1998
- 75. Invited Speaker, "The Development of Anticancer Agents." Guest Professor, XII Oncology Centroamerican and Caribbean Congress and Integrated Congresses, Antigua, Guatemala. October 1998
- 76. Invited Speaker, "Chemotherapy in Lung Cancer. New Perspectives?" Guest Professor, XIV meeting of the Mexican National Cancer Institute, Merida, Yucatan. 1997
- 77. Guest Professor, "Fluorinated Pyrimidines and Inhibitors of Thymidilate Synthase: New Agents and New Strategies.", New drugs and therapeutic combinations in gastrointestinal tumors symposium, Buenos Aires, Argentina. 1997

- 78. Master Conference, "New Drugs in the Treatment of Cancer." XIV Meeting Mexican national Cancer Institute, Merida, Yucatan. 1997
- 79. Guest Profesor, "New Drugs: An update.", XIII Congreso Argentino de Oncologia Clinica, Buenos Aires, Argentina. October 1997
- 80. Guest Profesor, "CPT-11.", XIII Congreso Argentino de Oncologia Clínica, Buenos Aires, Argentina. October 1997
- 81. Plenary Session, "Irinotecan for Metastatic Colorectal Cancer After Treatment with 5FU, Efficacy and Toxicity." X Brazilian Congress of Clinical Oncology, Sao Paulo, Brazil. June 1997
- 82. Guest Professor, "Irinotecan: Toxicity and Efficacy." New drugs and therapeutic combinations in gastrointestinal tumors symposium, Buenos Aires, Argentina. March 1997
- 83. Master Conference, "Non Small Cell Lung Cancer. Where are we? Where are we going?". Mexican Society of Oncological Studies, Mexico City. Mexico. 1997
- 84. Guest Professor, "Medical treatment of Colorectal Cancer.", Internacional Course of Gastroenterology, Monterrey, Mexico. 1996
- 85. Guest Professor, "Pancreatic cancer, Chemotherapy, Radiotherapy or Both.", Internacional Course of Gastroenterology. 1996
- 86. Invited Speaker."Phase I and II trials of Gemcitabine in pancreatic, lung and other cancers." Grand Rounds, Sylvester Comprehensive Cancer Center, Miami, Florida. 1996
- 87. Guest Professor, "New Strategies in Gastro-intestinal Tract Cancers.", XI Oncology Centroamerican and Caribbean Congress and Integrated Congresses, Santo Domingo Dominican Republic. October 1996
- 88. Guest Professor, "New Drugs in the Fight Against Cancer." XI Oncology Centroamerican and Caribbean Congress and Integrated Congresses, Santo Domingo Dominican Republic. October 1996
- 89. Invited Speaker, "The 5-α Reductase deficiency syndrome: From pseudo-Hermafroditism to cancer prevention." GU committee, Southwest Oncology Group Meeting, Phoenix Arizona. 1995
- 90. Invited Speaker, "Incomplete androgen insensitivity, first cases studied in the Dominican Republic." IV Student Congress on Scientific Research, San Juan, Puerto Rico. 1986

Research Interest

Thoracic Malignancies
Drug Development - Phase I/II Clinical trials
Experimental Therapeutics/Translational Research
Molecular Targeted Therapy
Modulation of Anticancer Drugs through Molecular Pharmacology

Description of Current Research Projects

Focus/Project 1: The identification of subgroups of patients who are exquisitely responsive to treatment with DNA breaking and molecularly targeted agents has led to the identification of pathways that are critical for DNA repair and of mutations that drive the malignancies. Dr Villalona's laboratory is conducting research in tumor specimens of patients undergoing surgery (breast, colon, ovarian, lung, prostatic, pancreatic and cervical cancer) to evaluate for an all inclusive method assessing the functionality of the Fanconi Anemia/BRCA pathway. An immunofluorescence-based test (FATSI) in paraffin embedded tissues, which could potentially lead to the identification of patients most likely to respond to DNA breaking agents or to agents inhibiting compensatory mechanisms of repair, has been developed and made available to the CLIA compliant Pathology Molecular core of OSUCCC. Collaboration with the NCI to test the effect of the PARP inhibitor ABT-888 in cancer cells and

fibroblasts deficient in this pathway and to identify synergistic molecules is underway. A human trial using selection by this strategy to treat cancer patients was activated and supported through a grant by the NCI/CTEP ACTNOW program. An NCI R01 to further explore this concept was awarded. 600 + pts have been screened, 60 pts have been enrolled in the therapeutic portion of the study. An R21 to study this concept in lung cancer was subsequently funded (Dr. Duan PI).

Focus Project 2: P53 mutation is one of the most common abnormalities in human malignancies. The laboratory of Dr. Villalona investigates potential strategies to restore the tumor suppressor activity of this gene. This includes the development of two mouse models of p53 mutations expressed exclusively in the lung through transgenic technology, and pioneering investigations in the role of the novel gene Pirh2 in P53 activation and the small molecule PRIMA 1 as promoter of p53-dependent apoptosis through regulation of microRNA 34a. Therapeutic interventions with PRIMA 1 to restore P53 function are being conducted on Dr. Villalona's laboratory. An R01 in this subject has been submitted.