BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.
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NAME	POSITION TITLE
Manuel Valdivieso, M.D. MS, CPE	Clinical Professor of Medicine University of Michigan Medical School Senior Executive Officer; Quality Assurance and International Initiatives Souhwest Oncology Group
eRA COMMONS USER NAME manuelva	

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

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
San Marcos University Medical School, Lima	M.D.	1961-1967	Medicine
Cook County Hospital, Chicago IL	Internship	1968-1969	Rotating Internship
Cook County Hospital, Chicago, IL	Resident	1969-1971	Internal Medicine
Cook County Hospital, Chicago, IL	Fellow	1971-1972	Hematology
Univ. of Texas, MD Anderson Cancer Center, Houston, TX	Fellow	1972-1974	Developmental Therapeutics
Graduate, University of Wisconsin	MS	1998-2000	Administrative Medicine

A. Personal Statement:

I am an experienced medical oncologist with expertise in thoracic malignancies, clinical trials design, multidisciplinary team's development and administrative medicine. I joined SWOG over five years ago as a Senior Executive Officer for Quality Assurance and International Initiatives. We have instituted the Quality Initiative Committee composed of physicians, operations office and statistical office representatives that meets with regularity throughout the year plus a formal meeting at each biannual Group Meeting. Through our efforts, we have succeeded by having the National Cancer Institutes of Mexico, Brazil, Colombia and Peru joining SWOG. Our goal is for them to become very active in clinical research at SWOG and eventually, for that experience to serve as an incentive to form their own independent Cancer Research Cooperative Group. I am a native from Peru and have ongoing professional relationships throughout Latin America. I am fluent in both, Spanish and English. I have developed interest in global health with particular focus on *Helicobacter pylori* infection and its relationship to gastric carcinoma. I became involved with an ongoing SWOG study of 1400 patients through a three arm randomized antibiotic trial designed to eradicate *H. pylori* in seven sites of Latin America. The study was conducted under the auspices of SWOG and the Melinda and Bill Gates Foundation. Two major publications in The Lancet and in JAMA have come out of this study. During the study, I researched the potential causes of *H. pylori* infection in Latin America and have found preliminary information relating the high incidence of *H. pylori* infection and gastric cancer to possible contaminated water in Lima, Peru. We hypothesized that applying modern molecular techniques to this problem we may shed light into the genotypic characterization of the infection and by so doing potentially linking the water contamination to the infection in humans. This is possible through collaboration with Chuanwu Xi, PhD, an expert on microbial speciation, from the U of M's Department of Public Health. In addition, I have established collaboration with Alejandro Bussalleu, MD, an academic gastroenterologist from the Cayetano Heredia Medical School in Lima, Peru, to facilitate the translational studies of this project. My interest on H. pylori is a departure from my prior clinical research interest in lung cancer and phase I chemotherapy.

B. Positions and Honors.

PROFESSIONAL APPOINTMENTS

1975 – 1983	Co-founder and Director of the medical oncology component of the first multidisciplinary thoracic oncology program at the MD Anderson Cancer Center, Houston, TX.
1978– 1980	Deputy Director, Cancer Clinical Research Center, The University of Texas System Cancer Center, MD Anderson Cancer Center, Houston, TX
1982– 1983	Chief, Section of Thoracic Medicine and Pulmonary Disease, Department of Internal Medicine, The University of Texas System, MD Anderson Cancer Center, Houston, TX
1986– 1992	Associate Director for Oncology, Division of Hematology and Oncology, Wayne State University, Harper Hospital, Detroit, MI
1986 – 1996	Founder and Director of the Multidisciplinary Thoracic Oncology Program at Wayne State University and the Karmanos Cancer Institute, Detroit, MI
1993– 1994	Interim Director, Division of Hematology and Oncology, Wayne State University, Harper Hospital, Detroit, MI
1994– 1996	Director, Division of Hematology and Oncology, Wayne State University, Harper Hospital, Detroit, MI
1996– 1999	Director, Cancer Center of Excellence, Oakwood Healthcare System, Dearborn, MI
1996– 2003	Associate Center Director for Clinical Investigations, University of Texas Southwestern, Dallas, TX
2004– 2008	Chief Medical Officer, Assoc. Director Clinical Affairs, Karmanos Cancer Institute, Detroit, MI
2009 – 2009	Medical Director, Extramural Programs, Karmanos Cancer Center, Detroit, MI
2010-Present	Senior Executive Officer for Quality Assurance and International Initiatives; SWOG; Ann Arbor, MI.

OTHER ACADEMIC EXPERIENCE

1974 – 1883	Faculty at the University of Texas MD Anderson Cancer Center, Houston, TX. From Faculty Associate to full Professor with tenure.
1986– 1996	Professor of Medicine with tenure at Wayne State University, Detroit, MI
1996– 1999	Adjunct Professor of Medicine at University of Michigan, Ann Arbor, MI
1999– 2003	Professor of Medicine with tenure at the University of Texas Southwestern, Dallas, TX
2003– 2003	Professor of Medicine with tenure at the Southern Illinois University, Springfield, IL
2003- 2009	Professor of Medicine with tenure, Wayne State University, Detroit, MI
2010 – Present	Clinical Professor of Medicine, University of Michigan, Ann Arbor, MI

HONORS

1996-Present	Best Doctors in America
2006-Present	America's Top Physicians
2011-2012	President, Peruvian American Medical Society
2015- Present	President, Directory, Policlinico of Peruvian American Society in Chincha, Peru

C. Contributions to Science:

My professional career spans almost four decades of clinical investigations ranging from supportive care studies (research on new antimicrobials in cancer patients, studies of intravenous hyperalimentation to minimize chemotherapy toxicities), investigation of chemotherapy dose-response in small cell lung cancer, Phase I clinical pharmacologic studies and, most recently, clinical laboratory studies on *Helicobacter pylori*. Other areas of studies have included combined modality studies in non-small cell lung cancer and studies of cardiotoxicity, including endomyocardial biopsies, of different treatment schedules of Doxorubicin in cancer patients. Many of these studies have been conducted under Phase I and Phase contracts with the NCI.

1. Research of new antimicrobials in cancer patients:

I had the opportunity of working with Dr. Gerald P. Bodey at MD Anderson Cancer Center and I was given the opportunity of working with him on a number of early studies of novel antimicrobials. My role was that of patient recruitment, close observation of patients after new antibiotic treatment, documentation and management of side effects if any, assistance with data collection, analysis of data and participation in manuscript preparation:

a. Valdivieso, M., Horikoshi, N., Rodriguez, V., Bodey, G.P. Therapeutic Trials with Tobramycin. Am. J. Med. Sci., 268:149-156, 1974.
b. Valdivieso, M., Feld, R., Rodriguez, V., Bodey, G.P. Amikacin Therapy of Infections in Neutropenic Patients. Am. J. Med. Sci., 270:453-463, 1975.
c. Valdivieso, M., Bodey, G.P., Feld, R., Rodriguez, V., Schwartz, P.B. In-Vitro, Pharmacological and Clinical Studies with Amikacin. Chemotherapy, 1:403-415, 1976
d. Valdivieso, M., Bodey, G.P. Amikacin Therapy of Severe Infections Produced by Gram-Negative Bacilli Resistant to Gentamicin. Am. J. Med. Sci., 273:177-184, 1977.

2. Studies of intravenous hyperalimentation in lung cancer patients:
I conducted these studies as a way to evaluate if improving the nutritional status of lung cancer patients would ameliorate the side effects of systemic chemotherapy for advanced disease. My role was that of study design, preparation of treatment protocol, supervision of data collection, analysis of data and preparation of manuscripts:

a. Issell, B.F., Valdivieso, M., Zaren, H.A., Dudrick, S.J., Freireich, E.J., Copeland, E.W., Bodey, G.P. Protection Against Chemotherapy Toxicity by IV Hyperalimentation. Cancer Treat. Rep., 62:1139-1143, 1978.
b. Jordan, W.M., Valdivieso, M., Frankman, C., Gillespie, M., Issel, B.F., Bodey, G.P., Freireich, E.J. Treatment of Advanced Adenocarcinoma of the Lung and Ftorafur, Doxorubicin, Cyclophosphamide and Cisplatin (FACP) and Intensive IV Hyperalimentation. Cancer Treat. Rep., 65:197-205, 1981.
c. Valdivieso, M., Bodey, G.P., Benjamin, R.S., Barkely, H.T., Freeman, M.B., Ertel, M., Smith, T.L., Mountain, C.V. Role of Intravenous Hyperalimentation as an Adjunct to Intensive Chemotherapy for Small Cell Bronchogenic Carcinoma. Preliminary Observations. Cancer Treat. Rep., 65:145-150, 1981.
d. Valdivieso, M., Frankmann, C., Murphy, W.K., Benjamin, R.S., Barkley, Jr., H.T., McMurtrey, M.J., Jeffries, D.G., Welch, S.R., Bodey, G.P. Long Term Effects of Intravenous Hyperalimentation Administered during Intensive Chemotherapy for Small Cell Bronchogenic Carcinoma. Cancer, 59:362-369, 1987.

3. Studies of chemotherapy dose –response in small cell lung cancer:
We extended our research to evaluate if "chemotherapy sensitive" cancers such as small cell lung cancer would respond better and more meaningfully to higher doses of chemotherapy taking advantage of the availability of protected environment –antibiotic units at MD Anderson and the presence of autologous bone marrow transplant capabilities. My role as leader of the medical component of the lung cancer program was that of contributing to study design, supervision of data collection, analysis and publication of data:

a. Farha, P., Spitzer, G., Valdivieso, M., Dicke, K.A., Zander, A., Dhingra, H.M., Minnhaar, G., Vellekoop, L., Verma, D.S., Umsawasdi, T., and Chiuten, D. High-Dose Chemotherapy and Autologous Bone Marrow Transplantation for the Treatment of Small Cell Lung Carcinoma. Cancer, 52:1351-1355, 1983.
b. Valdivieso, M., Cabanillas, F., Keating, M., Barkley, H.T., Murphy, W.K., Burgess, M.A., Frazier, H., Chen, T., Bodey, G.P. Effects of Induction Chemotherapy for Extensive-Disease Small Cell Bronchogenic Carcinoma in Protected Environment-Prophylactic Antibiotic Units. Am. J. Med., 76:405-412, 1984.
c. Spitzer, C., Farha, P., Valdivieso, M., Dicke, K., Zander, A., Vellekoop, L., Murphy, W.K., Dhingra, H.M., Umsawasdi, T., Chiuten, D., Carr, D.T. High-Dose Intensification Therapy with Autologous Bone Marrow Support for Limited Small- Cell Bronchogenic Carcinoma. J. Clin. Oncol., 4:4-13, 1986.
d. Spitzer, G., Valdivieso, M., Farha P., Murphy, W.K., Dhingra, H.M., Chiuten, D., Umsawasdi, T. Holoye, P. I.V. Melphalan in Carcinoma of the Lung: Effect of Cyclophosphamide Priming on Hematopoietic Toxicity. Cancer Treat. Rep., 70(4):449-453, 1986.

4. Phase I clinical pharmacologic studies of new chemotherapy:

These studies have been conducted over many years and mainly at MD Anderson Cancer Center in Houston, Texas, and at the Karmanos Cancer Institute in Detroit, Michigan. Some were conducted by myself as a first author and many as part of the Phase I team of those institutions. My role changed over the years from first author in charge of writing and conducting the treatment protocol to that of support and contribution to patient accrual and review of data. Examples of those studies are:

a. Valdivieso, M., Bodey, G.P., Gottlieb, J.A., Freireich, E.J. Clinical Evaluation of Ftorafur. Cancer Res., 36:1821-1824, 1976.
b. Valdivieso, M., Moore, E.C, Burgess, A.M., Marti, J.R, Russ, J., Plunkett, W., Loo, T.L., Bodey, G.P., Freireich, E.J. Phase I Clinical Study of N-(Phospho-Nacetyl) L -Aspartic Acid (PALA). Cancer Treat. Rep., 64:285-292, 1980.
c. Valdivieso, M., Bedikian, A.Y., Burgess, M.A., Savaraj, N., Jeffers, W.B., Bodey, G.P. Phase I Clinical Study of Dihydroxyanthracenedione Administered on a 5-day IV Schedule. Cancer Treat. Rep., 65:841-844, 1981.
d. Heath E, LoRusso P, Ramalingam SR, Awada A, Egorin MJ, Besse-Hamer T, Cardoso F, Valdivieso M, Has T, Alland L, Zhou X, Belani ChP. "A Phase I Study of BMS-275183, a novel oral analogue to Paclitaxel given on a daily schedule to patients with advanced malignancies". Invest New Drugs 2011; 29: 1426-1431.

5. Clinical Laboratory studies on *Helicobacter pylori*:

I am a member of a team of investigators within SWOG that over several years has worked to develop collaborative clinical research working relationships with National Cancer Institute equivalents of Latin America. To date, the National Cancer Institutes of Mexico, Colombia and Peru have joined SWOG and are actively involved in Group's clinical trials. The long-term goal of these efforts is to facilitate the development of an independent Cancer Clinical Research Cooperative Group in Latin America in a way similar to the EORTC. Latin America has unique infectious related cancers that should be studied as they may affect the US in the future. Consequently, we have conducted a prospective randomized antibiotic clinical trial designed to eradicate *Helicobacter pylori (H. pylori*) that is considered a causative agent of gastric carcinoma. Seven sites in six countries have participated. Since gastric cancer is prevalent in Latin America, the eradication of this infection becomes important. Under my leadership, we have further extended this study to conduct a primary prevention clinical laboratory study designed to investigate if the drinking water in Lima, Peru, is contaminated with *H. Pylori*. We have molecular evidence of *H. pylori* presence of the drinking water of certain areas of Lima, Peru, and such observation have been extended to experimental studies of *H. pylori* infection in mice .

a. Greenberg, E.R., Anderson, G.L., Morgan, D.R., Torres, J., Chey, W.D., Bravo, L.E., Dominguez, R.L., Ferreccio, C., Herrero, R., Lazcano-Ponce, E.C., Meza-Montenegro, M.M., Pena, E.M., Pena, E.M., Salazar- Martinez, E., Correa, P., Martinez, M.E., Valdivieso, M., Goodman, G.E., Baker, L.H. 14-day triple, 5-day concomitant and 10-day sequential therapies for Helicobacter pylori infection in seven Latin American sites: a randomized trial. Published on line by The Lancet on July 20, 2011. DOI: 10.1016/S0140-6736 (11) 60825-8.
b. Morgan, R.D., Torres, J., Sexton, R., Herrero, R., Salazar-Martinez, E., Greenberg, E.R., Bravo, L.E., Dominguez, R.L., Ferreccio, C., Lazcano-Ponce, E.C., Maza-Montenegro, M.M., Peña, E.M., Peña, R., Correa, P., Martinez, M.E., Chey, W.D., Valdivieso, M., Anderson, G.L., Goodman, G.E., Crowley, J.J., Baker, L.H. Risk of Recurrent Helicobacter pylori Infection 1 Year After Initial Eradication Therapy in 7 Latin American Communities. JAMA, 2013; Vol 309; No 6: 578 – 586.
c. Boehnke KF1, Eaton KA, Valdivieso M, Baker LH, Xi C. Animal Model Reveals Potential Waterborne Transmission of Helicobacter pylori Infection. Helicobacter. 2015 Feb 9. doi: 10.1111/hel.12216. [Epub ahead of print]
d. Valdivieso, M, Bussalleu, A, Sexton, R, Boehnke, K, Osorio, S, Novoa I, Crowley J, Goodman, G, Baker, L, and Xi, C. Clinical, Epidemiologic, and Genomic Studies (SWOG S1119) of *Helicobacter Pylori* in Lima, Peru: Role of Contaminated Water. J. of Cancerol. 2016; 2:52-63.

D. Additional Information: Research Support and/or Scholastic Performance

CURRENT SUPPORT:

U01CA180888 (PI: Blanke) 03/01/2014 – 02/28/2019
OHSU/ NIH
SWOG Network Group Operations Center of the NCTN - subcontract site
Goals: The goal of this project is to provide support for specific University of Michigan faculty who serve in leadership positions in the SWOG Network Group Operations Center.
Role: Co-I (25.70% effort)
Annual Directs: $208,881

UG1CA189974 (PI: Blanke) 08/01/2014 – 07/31/2019
OHSU / NIH
SWOG NCORP Research Base
Goals: SWOG NCORP Research Base will collaboratively design and develop clinical trial protocols relating to Cancer Prevention, Cancer Control, and Cancer Care Delivery.
Role: Co-I (24.80% effort)
Annual Directs: $78,300

15-PAF03902 (PI: Valdivieso)
The Hope Foundation 03/01/2014 – 02/28/2019
SWOG Clinical Trials Initiative
Goals: The goal of this project is to provide salary support for Dr. Manuel Valdivieso who serves in leadership positions in SWOG, including SWOG Clinical Trials Initiatives (CTI).
Role: PI (18.50% effort)
Annual Directs: $41,701