BIOGRAPHICAL SKETCH

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NAME: Giralt, Sergio

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

POSITION TITLE: Deputy Division Head, Division of Hematologic Malignancies

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

INSTITUTION AND LOCATION	DEGREE (if applicable)	Completion Date MM/YYYY	FIELD OF STUDY
Universidad Central de Venezuela, Escuela Luis Razetti, Caracas, Miranda	MD	07/1984	Medicine
c, Cincinnati, OH	Resident	06/1987	PGY1 Internal Medicine
Good Samaritan Hospital, Cincinnati, OH	Resident	06/1988	PGY 2 Internal Medicine
Good Samaritan Hospital, Cincinnati, OH	Resident	06/1989	PGY 3 Internal Medicine
University of Texas MD Anderson Cancer Center, Houston, TX	Fellow	06/1993	PGY4-5-6-7 Hematology/Oncology

A. Personal Statement

I have been involved in the field of hematopoietic cell transplantation (HCT) for more than 30 years. I am currently the Deputy Division Head, Division of Hematologic Malignancies and an Attending Physician on the Adult Bone Marrow Transplant (BMT) Service at MSK. I have held leadership positions in major national organizations such as the Center for International Blood and Marrow Transplant Research (Chair of the Advisory Board), the Blood and Marrow Transplant Clinical Trials Network (BMT-CTN), and most recently President Elect of the American Society of Blood and Marrow Transplantation. My clinical research career has focused in three areas: 1) Developing better tolerated conditioning regimens for older or medically infirmed patients with hematological malignancies to allow them access to this procedure; 2) Developing novel HCT therapies (conditioning regimens plus post-transplant therapies) for autologous and allogeneic HCT for myeloma and 3) Pursue strategies that will significantly reduce HCT symptom burden and toxicities. As Chief of the Adult BMT Service, I have had extensive experience designing, implementing and performing HCT studies both as a principal investigator and as a collaborator. For this project I will lead the protocol at MSKCC, supervise the research staff as well as accrue patients to the clinical trial. I will provide HCT clinical expertise and symptom burden post-transplant.

1. Landau H, Wood K, Chung DJ, Koehne G, Lendvai N, Hassoun H, Lesokhin A, Hoover E, Zheng J, Devlin SM, Giralt S. Fractionated stem cell infusions for patients with plasma cell myeloma undergoing autologous hematopoietic cell transplantation. Leuk Lymphoma. 2016 Aug;57(8):1781-5. PubMed PMID: 26758672.
2. Shah N, Callander N, Ganguly S, Gul Z, Hamadani M, Costa L, Sengsayadeth S, Abidi M, Hari P, Mohty M, Chen YB, Koreth J, Landau H, Lazarus H, Leather H, Majhail N, Nath R, Osman K, Perales MA, Schriber J, Shaughnessy P, Vesole D, Vij R, Wingard J, Giralt S, Savani BN. Hematopoietic Stem Cell Transplantation for Multiple Myeloma: Guidelines from the American Society for Blood and Marrow Transplantation. Biol Blood Marrow Transplant. 2015 Jul;21(7):1155-66. PubMed PMID: 25769794.
3. Shah N, Ahmed F, Bashir Q, Qureshi S, Dinh Y, Rondon G, Wen S, Thall P, Khan H, Giralt S, Champlin R, Qazilbash MH. Durable remission with salvage second autotransplants in patients with multiple myeloma. Cancer. 2012 Jul 15;118(14):3549-55. PubMed PMID: 22086552; PubMed Central PMCID: PMC4038445.
4. Cleeland CS, Allen JD, Roberts SA, Brell JM, Giralt SA, Khakoo AY, Kirch RA, Kwitkowski VE, Liao Z, Skillings J. Reducing the toxicity of cancer therapy: recognizing needs, taking action. Nat Rev Clin Oncol. 2012 Jul 3;9(8):471-8. PubMed PMID: 22751283.

B. Positions and Honors

Positions and Employment

1989 - 1992	Medical Oncology Fellow, Univeristy of Texas MD Anderson Cancer Center, Houston, TX
1992 - 1993	Chief Medical Oncology Fellow, University of Texas MD Anderson Cancer Center, Houston, TX
1992 - 1993	Junior Faculty Associate, Universtiy of Texas MD Anderson Cancer Center, Houston, TX
1993 - 1995	Instructor/Assistant Internist, University of Texas MD Anderson Cancer Center, Houston, TX
1996 - 1998	Assistant Professor of Medicine/Assistant Internist, University of Texas MD Anderson Cancer Center, Houston, TX
1998 - 2003	Associate Professor of Medicine, University of Texas MD Anderson Cancer Center, Houston, TX
1999 - 2004	Hematology Co Center Director and Clinic Chief, University of Texas MD Anderson Cancer Center, Houston, TX
2003 - 2010	Deputy Chair Department of Blood and Marrow Transplantation, University of Texas MD Anderson Cancer Center, Houston, TX
2003 - 2010	Professor of Medicine, University of Texas MD Anderson Cancer Center, Houston, TX
2010 - 2020	Chief Attending, Adult BMT Service, Memorial Sloan Kettering Cancer Center, New York City, NY
2020 –	Deputy Division Chief Division of Hematologic Malignancies Memorial Sloan Kettering Cancer Center, New York City
2011 -	Professor of Medicine, Weill Cornell Medical College, New York City, NY
2011 -	Attending Physician Memorial Hospital, New York City

Other Experience and Professional Memberships

2006 - 2010	Chair Elect/Chair/Past Chair, Center for International Blood and Marrow Transplant Research (CIBMTR)
2009 - 2012	Chair Elect/Chair/Past Chair, Blood and Marrow Transplant Clinical Trials Network (BMT-CTN)
2012 -	Member, National Cancer Institute Myeloma Steering Committee
2012 - 2016	Vice President/President Elect/President/Past President, American Society of Bloor and Marrow Transplant (ASBMT)
2015 -	Member, Advisory Council on Blood Stem Cell Transplantaton for the Health Resource Service Administration
2015 -	Member of the Advisory Council on Blood and Stem Cell Transplantation, Health Resource Service Administration

Honors

1990	University of Texas Cancer Foundation Award, University of Texas MD Anderson Cancer Center
1991	University of Texas MD Anderson Cancer Center Achievement in Research Award, University of Texas MD Anderson Cancer Center
2005	Jenaro Haddock Lecture, Puerto Rican Society of Hematology and Oncology
2011	Joseph R and Nancy Bove Transfusion Medicine Visiting Professorship, Yale University
2013	E Donnell Thomas Award, The Bone Marrow Foundation

C. Contribution to Science

1. Optimizing Chronic Myelogenous Leukemia Therapy: My first major contribution was to demonstrate that prior interferon therapy did not affect outcomes of allogeneic HCT. This allowed patients and physicians to attempt to achieve a complete cytogenetic remission without the need of an allograft. These observations remain relevant in the era of tyrosine kinase inhibitors (i.e. imatinib) since these studies showed that delaying HCT in patients with CML did not affect HCT outcomes as long as patients were carefully monitored and were responding to treatment.

a. Giralt S, Szydlo R, Goldman JM, Veum-Stone J, Biggs JC, Herzig RH, Klein JP, McGlave PB, Schiller G, Gale RP, Rowlings PA, Horowitz MM. Effect of short-term interferon therapy on the outcome of subsequent HLA-identical sibling bone marrow transplantation for chronic myelogenous leukemia: an analysis from the international bone marrow transplant registry. Blood. 2000 Jan 15;95(2):410-5. PubMed PMID: 10627443.

2. Treatment and Prevention of Relapse Post HCT: Relapse is the most common cause of treatment failure post autologous and allogeneic HCT. I wrote one of the first major reviews on this issue and have led multiple studies looking at strategies to prevent or treat relapse post HCT. I was a major contributor to the CALGB

   100104 trial that demonstrated the efficacy of lenalidomide in preventing myeloma relapse post HCT, and pioneered the use of 5 azacytidine to prevent relapse post allogeneic HCT for AML or MDS. Together with Drs Bishop, Wayne and Kroeger we have organized the 1st, 2nd and 3rd International Workshops on the treatment and prevention of relapse post HCT. These efforts have now resulted in numerous phase I/II and III trials exploring various strategies to prevent relapse post HCT.

   a. de Lima M, Porter DL, Battiwalla M, Bishop MR, Giralt SA, Hardy NM, Kröger N, Wayne AS, Schmid C. Proceedings from the National Cancer Institute's Second International Workshop on the Biology, Prevention, and Treatment of Relapse After Hematopoietic Stem Cell Transplantation: part III. Prevention and treatment of relapse after allogeneic transplantation. Biol Blood Marrow Transplant. 2014 Jan;20(1):4-13. PubMed PMID: 24018392; PubMed Central PMCID: PMC3938421.
   b. McCarthy PL, Owzar K, Hofmeister CC, Hurd DD, Hassoun H, Richardson PG, Giralt S, Stadtmauer EA, Weisdorf DJ, Vij R, Moreb JS, Callander NS, Van Besien K, Gentile T, Isola L, Maziarz RT, Gabriel DA, Bashey A, Landau H, Martin T, Qazilbash MH, Levitan D, McClune B, Schlossman R, Hars V, Postiglione J, Jiang C, Bennett E, Barry S, Bressler L, Kelly M, Seiler M, Rosenbaum C, Hari P, Pasquini MC, Horowitz MM, Shea TC, Devine SM, Anderson KC, Linker C. Lenalidomide after stem-cell transplantation for multiple myeloma. N Engl J Med. 2012 May 10;366(19):1770-81. PubMed PMID: 22571201; PubMed Central PMCID: PMC3744390.
   c. de Lima M, Giralt S, Thall PF, de Padua Silva L, Jones RB, Komanduri K, Braun TM, Nguyen HQ, Champlin R, Garcia-Manero G. Maintenance therapy with low-dose azacitidine after allogeneic hematopoietic stem cell transplantation for recurrent acute myelogenous leukemia or myelodysplastic syndrome: a dose and schedule finding study. Cancer. 2010 Dec 1;116(23):5420-31. PubMed PMID: 20672358.

3. Development of More Effective Conditioning Regimens for HCT: One of the main focuses of my research career has been the development of novel conditioning regimens that would be more effective for patients with myeloma or myeloid leukemias. Initially I explored more intense combinations, however, quickly realized that very intense myeloablative regimens would preclude the use of HCT in older and debilitated patients which represent the majority of patients with hematologic malignancies. I was one of the first proponents of reduced intensity conditioning regimens and developed one of the most common regimens used today (fludarabine/melphalan). The development of RIC regimens has allowed for hundreds of patients to undergo allogeneic HCT and has been a true change in the standard of care. I am recognized as an international leader and expert in the field and have been heavily involved in educating physicians and third party payers to encourage early referral of older patients with myeloid leukemias to HCT. In myeloma I have also been a leader in developing new regimens to improve upon the results of the current gold standard of single agent melphalan.

   a. Popat U, de Lima MJ, Saliba RM, Anderlini P, Andersson BS, Alousi AM, Hosing C, Nieto Y, Parmar S, Khouri IF, Kebriaei P, Qazilbash M, Champlin RE, Giralt SA. Long-term outcome of reduced-intensity allogeneic hematopoietic SCT in patients with AML in CR. Bone Marrow Transplant. 2012 Feb;47(2):212-6. PubMed PMID: 21423123; PubMed Central PMCID: PMC4320641.
   b. McClune BL, Weisdorf DJ, Pedersen TL, Tunes da Silva G, Tallman MS, Sierra J, Dipersio J, Keating A, Gale RP, George B, Gupta V, Hahn T, Isola L, Jagasia M, Lazarus H, Marks D, Maziarz R, Waller EK, Bredeson C, Giralt S. Effect of age on outcome of reduced-intensity hematopoietic cell transplantation for older patients with acute myeloid leukemia in first complete remission or with

myelodysplastic syndrome. J Clin Oncol. 2010 Apr 10;28(11):1878-87. PubMed PMID: 20212255; PubMed Central PMCID: PMC2860368.

c. Giralt S, Estey E, Albitar M, van Besien K, Rondón G, Anderlini P, O'Brien S, Khouri I, Gajewski J, Mehra R, Claxton D, Andersson B, Beran M, Przepiorka D, Koller C, Kornblau S, Kørbling M, Keating M, Kantarjian H, Champlin R. Engraftment of allogeneic hematopoietic progenitor cells with purine analog-containing chemotherapy: harnessing graft-versus-leukemia without myeloablative therapy. Blood. 1997 Jun 15;89(12):4531-6. PubMed PMID: 9192777.

4. Reducing HCT Symptom Burden: High dose therapy with autologous or allogeneic hematopoietic stem cell support is associated with very high levels of symptom burden that have a significant negative impact on patients quality of life and for many patients a major barrier to proceeding to a potential life saving therapy. Together with Dr. Charles Cleeland at MDACC I was part of a team of investigators who have made substantial inroads into understanding the biology behind symptom burden, we also developed prospective intervention trials that have served as model for other investigators. I have continued to pursue this line of investigation and extended it to collaborations with integrative medicine (see Deng et al) and caregiver experiences through my collaborations with Drs Applebaum and Duhamel.

   a. Landau H, Wood K, Chung DJ, Koehne G, Lendvai N, Hassoun H, Lesokhin A, Hoover E, Zheng J, Devlin SM, Giralt S. Fractionated stem cell infusions for patients with plasma cell myeloma undergoing autologous hematopoietic cell transplantation. Leuk Lymphoma. 2016 Aug;57(8):1781-5. PubMed PMID: 26758672.

   b. Shah N, Shi Q, Williams LA, Mendoza TR, Wang XS, Reuben JM, Dougherty PM, Bashir Q, Qazilbash MH, Champlin RE, Cleeland CS, Giralt SA. Higher Stem Cell Dose Infusion after Intensive Chemotherapy Does Not Improve Symptom Burden in Older Patients with Multiple Myeloma and Amyloidosis. Biol Blood Marrow Transplant. 2016 Feb;22(2):226-31. PubMed PMID: 26253006; PubMed Central PMCID: PMC4716870.

   c. Applebaum AJ, Bevans M, Son T, Evans K, Hernandez M, Giralt S, DuHamel K. A scoping review of caregiver burden during allogeneic HSCT: lessons learned and future directions Bone Marrow Transplant. 2016 Nov;51(11):1416-1422. doi: 10.1038/bmt.2016.164. Epub 2016 Jun 13.

   d. Deng G, Giralt S, Chung DJ, Landau H, Siman J, Search B, Coleton M, Vertosick E, Shapiro N, Chien C, Wang XS, Cassileth B, Mao JJ. Acupuncture for reduction of symptom burden in multiple myeloma patients undergoing autologous hematopoietic stem cell transplantation: a randomized sham-controlled trial. Support Care Cancer. 2018 Feb;26(2):657-665. doi: 10.1007/s00520-017-3881-7. Epub 2017 Sep 17. PMID: 28920142

5. Developing a Large Cooperative Group Network to perform HCT Trials: The Blood and Marrow Transplant Clinical Trials Network (BMT CTN) was established in October 2001 with resources from the National Heart Lung and Blood Institute and the National Cancer Institute to perform practice changing clinical trials in the HCT field. Since its inception the BMT-CTN has opened more than 30 protocols that have accrued more than 6000 patients. These efforts have resulted in major practice changing observations that arose from the design and completion of large randomized phase III trials. Thanks to these trials we learned that: 1. Lenalidomide maintenance dramatically improves progression free survival and overall survival in patients undergoing autografts for myeloma. 2. Use of unrelated donor peripheral blood stem cells increases the risk of chronic graft versus host disease without providing survival or progression free survival advantage over unrelated bone marrow. 3. Allogeneic HCT with a low dose TBI containing regimen after an initial autologous HCT offers no clinical benefit when compared to a second autograft in patients with standard risk myeloma. I have been heavily involved with the BMT-CTN since its inception and was Chair of the Steering Committee from 2008 – 2010. I created the BMTCTN-Myeloma Intergroup Committee that coordinates research efforts of different cooperative groups to optimize use of resources and avoid competing trials.

   a. Devine SM, Owzar K, Blum W, Mulkey F, Stone RM, Hsu JW, Champlin RE, Chen YB, Vij R, Slack J, Soiffer RJ, Larson RA, Shea TC, Hars V, Sibley AB, Giralt S, Carter S, Horowitz MM, Linker C, Alyea EP. Phase II Study of Allogeneic Transplantation for Older Patients With Acute Myeloid Leukemia in First Complete Remission Using a Reduced-Intensity Conditioning Regimen: Results From Cancer and Leukemia Group B 100103 (Alliance for Clinical Trials in Oncology)/Blood and Marrow Transplant

Clinical Trial Network 0502. J Clin Oncol. 2015 Dec 10;33(35):4167-75. PubMed PMID: 26527780; PubMed Central PMCID: PMC4658453.

b. Appelbaum FR, Anasetti C, Antin JH, Atkins H, Davies S, Devine S, Giralt S, Heslop H, Laport G, Lee SJ, Logan B, Pasquini M, Pulsipher M, Stadtmauer E, Wingard JR, Horowitz MM. Blood and marrow transplant clinical trials network state of the Science Symposium 2014. Biol Blood Marrow Transplant. 2015 Feb;21(2):202-24. PubMed PMID: 25445636; PubMed Central PMCID: PMC4426907.

c. Giralt S, McCarthy PL, Anderson KC, Carter SL, Richardson PG, Rajkumar SV, Laport GG, Stadtmauer EA, Pasquini MC, Horowitz MM. Anatomy of a successful practice-changing study: a Blood and Marrow Transplantation Clinical Trials Network-National Cancer Institute Cooperative Group collaboration. Biol Blood Marrow Transplant. 2013 Jun;19(6):858-9. PubMed PMID: 23545332; PubMed Central PMCID: PMC4426902.

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

Ongoing Research Support

GC240968 (PI: Deng) 1.20 calendar
Patient Centered Outcomes Research Institute
5/1/2020 - 4/30/2023
$ 846,026
Opioid-sparing Pain Treatment In Myeloma And Lymphoma Patients Undergoing High-Dose Chemotherapy (OPTIMAL-HiChemo)
The overall goal of the proposed research is to improve management of pain caused by cancer treatment. Specifically, with input from patients and clinician stakeholders, we would like address this patient-centered question: “Would using acupuncture to prevent pain during cancer treatment reduce opioid use and opioid side effects without compromising pain control?”
Role: Co-Investigator
GC240732 (PI: Giralt) 0.00 calendar
Parker Institute for Cancer Immunotherapy - MSK
7/1/2019 - 6/30/2020
$ 75,000
Identifying the effects of ipilimumab on T cell reconstitution and anti-myeloma effects in in patients with relapsed/refractory multiple myeloma undergoing allogeneic hematopoietic stem cell transplantation
Role: Principal Investigator

Role: Principal Investigator
GC241575 (PI: Lin) 0.50 calendar
Dresner Foundation
10/1/2019 - 9/30/2022
$ 106,250
Phase II Study of a Geriatric Vulnerability Based, Personalized Allogeneic Hematopoietic Transplantation Strategy for Older, Vulnerable Patients with Myelodysplastic Syndrome
Myelodysplastic syndrome (MDS) predominantly affects older adults. Allogeneic hematopoietic cell transplantation- from a genetically similar donor-is the only curative treatment option, yet in older patients its use is limited by increased treatment-related toxicities and early mo1tality. Therefore, there is a critical need to develop effective approaches to select older candidates, to adjust transplant strategies to accommodate geriatric deficits, and to manage aging-related issues before.
Role: Co-PI
GC233280 (PI: Peled) 0.00 calendar