



CLINICAL RESEARCH CENTER

Mission Statement

Dr. Jose M Mandry has been in the greater Orlando area since 1989, and involved in research since early 1990. Dr. Jose M Mandry has been the Principal Investigator of research studies since 2010. He is the president of West Orange Endocrinology, P.A., incorporated September 2018.

Vision

The staff at West Orange Endocrinology (WOE) are committed to serve the community by offering the latest in treatment modalities and to become the leader in endocrine research in Central Florida. WOE is dedicated to improving the process of delivering services that enhance patient outcomes.

Mission

Patient satisfaction and safety is of utmost importance, and we can achieve all objectives through sound, ethical and quality clinical research. We strive to provide patients with new technology and innovative strategies that will provide optimal or superior health outcomes. We have found that inviting our patients to participate in clinical research has led to a positive outcome for patients and has enhanced the public perception of our practice.

Values

Provide medical care using a holistic and compassionate approach.
Recognize each patient as a unique individual and serve them with integrity and professionalism.
Demonstrate leadership, teamwork and collaboration with staff, client and sponsor.
Mentor and collaborate with other medical professionals.

Clinical research

Endocrinology and metabolic studies are recognized as part of a universal core objective in understanding the process of mitigation, health maintenance and/or treatment of chronic diseases. WOE is dedicated to mitigating the devastating effects resulting from diabetes, obesity, hypertension, metabolic diseases and lipid disorders. Together, and in conjunction with renowned scientists, academia, and specialists from other research institutes, WOE, P.A. Clinical Research contributes to advances in this field of medical research.

WOE, P.A. investigators have been involved in international conferences, scientific meetings and important forums highlighting recent research projects and presenting scientific publications. Association among professionals in research encourages stimulating discussions while sharing vital information with colleagues. Our experiences and accomplishments have been published in full scientific journals. These investigations exceptionally impact regional and international standards of practice through new discoveries and developments.

With increasing maturity, experience and associations in the industry, we have evolved into industry-sponsored (ISRs) programs. At WOE, P.A. our associations with the Clinical Research Organization (CRO) and pharmaceutical industries, WOE, P.A. has become well recognized because of the commitment demonstrated in collaboration with CRO to a successful clinical trial program.

As we grow and embark on new research programs, we continue to develop and culminate the optimal culture for good clinical practices in research. Compliance with GCP, safety and optimization treatment of our clients are the main goals. We are honored to be of service to the community to offer new products and opportunities to our patients and to provide meaningful information to other scientists, physicians and research investigators.

Our team of qualified staff members maintain a low failure rate for screening patients and for lost to follow-up. Our staff keeps subjects on tract with frequent phone reminders and messages. We have a high enrollment in studies and reach or surpass our expectations. Some of our studies have been capped early due to high enrollment. We are proud to have high enrollment, good retention as well as good quality data.

CLINICAL RESEARCH CENTER TEAM

Jose M Mandry, MD.....Principal Investigator

Jose M. Mandry, M.D Endocrinology and Metabolism
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PROFESSIONAL EXPERIENCE

EMPLOYMENT

1. Roger Williams Medical Center And Bristol County Medical Center, Bristol, RI Emergency Room Physician December 1989 to June 1991
2. Private Practice in Endocrinology and Metabolism, Beaumont, Texas July 1991 to June 1992
3. Private Practice in Endocrinology and Metabolism in Ocoee, FL West Orange Endocrinology, P.A. (Endocrine Associates of FL, P.A.) Ocoee, Florida July 1992 to present
4. Medical Expert Consultant for the Florida Department of Health and for the U.S. Department of Justice 2001 to present
5. Principal investigator for Arthritis Center of Orlando, Ocoee, Fl. USA November 2017 to 2019

EDUCATION

UNIVERSITY

Washington University in St. Louis, MO BS, Biology, December 1981

MEDICAL SCHOOL

Ponce School of Med. Ponce, PR. M.D., May 1986

RESIDENCY

St. Vincent's Medical Center, Bridgeport, CT Affiliate of Yale University, July 1986 to June 1989
Internal Medicine

FELLOWSHIP

Roger Williams Medical Center and Rhode Island Hospital, Providence, RI Affiliates of Brown University, July 1989 to June 1991 Endocrinology and Metabolism

PROFESSIONAL RESEARCH TRAINING

1. AACE Clinical Research Workshop Washington, DC Sept. 28-30, 2012
2. GCP certification Brookwood International Institute May, 2019
3. GCP certification training for investigational sites Boehringer Ingelheim Aug, 2021

CERTIFYING EXAMINATIONS

1. Diplomat of National Boards of Medical Examiners, March 1987
2. Diplomat of the American Board of Internal Medicine, Sept. 1989
3. Certified in radioisotope handling for Nuclear Medicine procedures, April 1991
4. Diplomat of the American Board of Internal Medicine, Subspecialty of Endocrinology and Metabolism, Nov. 1991 and re-certified, Nov. 2000 and Nov. 2010 and Sep. 2020.

ACTIVITIES/MEMBERSHIPS

1. American Medical Student Association Member 1982-1986
2. Treasurer, American Med. Student Assoc. Ponce School of Medicine Section, 1982-1983
3. Class Treasurer, Ponce School of Med., 1982-1983
4. Class Vice-President, Ponce School of Medicine, 1983-1984
5. Alternate Delegate for Ponce School of Med. at the American Medical Association's annual meeting At Chicago, Illinois. June 1984
6. Member of the Physician-Nursing Liaison Committee. St. Vincent's Medical Center, 1987-1988
7. Alpha Omega Alpha (AOA), Ponce School of Med. 1990

8. Medical Director of Diabetes Lifestyle: Diabetes Outpatient Education and Treatment Center. St Elizabeth Hospital, Beaumont, Texas. 1991-1992
9. Medical Director of St. Elizabeth Hospital's Osteoporosis Detection and Treatment Center. Beaumont, Texas. 1991-1992
10. Member Board of Directors for the Southeast Texas Chapter of the American Medical Association. 1991-1992
11. Co-Chairman of Mile of Quarters Campaign: Fund raiser for American Diabetes Association. March, 1992
12. Member of the American Association of Clinical Endocrinology (AACE). 1992-present.
13. Fellow of the American College of Endocrinology (FACE). 1993-present.
14. Member, Pan-American Medical Association of Central Florida (PAMACFL), 2004-2021.
15. Treasurer. PAMACFL. 2005 President. PAMACFL. 2006 Vice President. PAMACFL, 2007
16. President, West Orange Endocrinology, P.A., 2019.

TEACHING EXPERIENCE/AWARDS

1. Assistant Instructor in Medicine, Brown University, Providence, RI. 1990-1991
2. Assistant Instructor of Endocrinology and Metabolism for Brown University Medical School. 1991
3. Attending Physician Internal Medicine Residency Program Division of Endocrinology. Orlando Regional Medical Center, Orlando, Fl. 1992-2011.
4. Clinical Assistant Professor in the Department of Clinical Sciences at the Florida State University College of Medicine. 2003-present
5. Assistant Professor of Medicine and Director of the Endocrinology outpatient clinical clerkship for FSU College of Medicine
6. Adjunct Clinical Faculty of Barry University Physician Assistant Program. 2007-8
7. Named as one of the Best Doctors in America. 2007-Present
8. Affiliate Agreement with the Univ. of South Florida, College of Nursing, for training of student nurses in clinical practice.
9. Provided 500 hours of training to a nurse practitioner from USF College of Nursing, 2007-8
10. Named as Best Doctor by Orlando Magazine 2007-2011.
11. Assistant Professor of Internal Medicine for UCF College of Medicine, 2009- present
12. Voted as one of the Best Doctors in America. 2007-2011

PRESENTATIONS

1. Premature Ovarian Failure. Inter-hospital grand rounds, Roger Williams Med. Center, Providence, RI. Oct. 1989
2. Panhypopituitarism. Inter-hospital grand rounds, RWMC, Providence, RI. March 1990
3. Nephrolithiasis. Medical house staff conference, RWMC, Providence, RI. June 1990
4. Prednisone/prednisolone pharmacokinetics. Inter-hospital grand rounds, RWMC, Providence, RI. June 1990
5. Familial medullary thyroid carcinoma. Inter-hospital grand rounds, Rhode Island Hospital, Providence, RI Sept. 1990
6. Cushing's Syndrome. Inter-hospital grand rounds, Rhode Island Hospital, Providence, RI. Jan. 1991
7. Primary Hyperaldosteronism. Inter-hospital grand rounds, RWMC. Providence, RI. Feb. 1991
8. Inappropriate secretion of TSH. Inter-hospital grand rounds, RWMC, Providence, RI. Feb. 1991
9. WFDM (CBS - Beaumont) Morning News. Television interviews on Aug 7, 14, 21 and 28, 1991.
Topics: Diabetes Mellitus, Osteoporosis, Thyroid dysfunction, and Paget's disease of bone.
10. Oral Agents in Diabetes Mellitus. St. Elizabeth Hospital Health Resource Center, Beaumont, Texas. Aug. 1991
11. Osteoporosis: are you at risk? Part one; the disease - Sept. 9 1991. Part two; the treatment - Sept. 16. 1991. St. Elizabeth Hospital Business and Education Center, Beaumont, Texas.

12. Osteoporosis. Medical Center of Winnie. Winnie, Texas. Sept 1991

13. Bone Density Measurements in Osteoporosis. Tyler County Hospital, Woodville, Texas. Sept. 1991
14. Diabetes Mellitus. Lions Club Meeting, Beaumont, Texas. Sept. 1991
15. Diabetic Ketoacidosis. Pediatric Critical Care Course, St. Elizabeth Hosp. Beaumont, Texas. Oct. 1991
16. Insulin Therapy in Diabetes Mellitus. St. Elizabeth Hospital Health Resource Center. Oct. 1991.
17. Hormonal Treatment in Osteoporosis. Conference Center of Winnie. Winnie, Texas. Oct. 1991.
18. Thyroid Storm, Myxedema Coma, SIADH, Diabetes Insipidus. Critical Care Course for Nursing Staff St. Elizabeth Hospital. Oct. 1991.
19. KFDM (CBS - Beaumont) Live at Five News Report. Television Interview on hypothyroidism Oct 29, 1991.
20. Hypothyroidism. St. Elizabeth Health Resource Center. Oct. 1991.
21. Calcium Therapy in Osteoporosis. St. Elizabeth Health Resource Center. Nov. 1991.
22. Osteoporosis. Beaumont State Center's Health Fair. Nov. 1991.
23. Paget's Disease of Bone. St. Elizabeth Health Resource Center. Dec. 1991.
24. KFDM (CBS- Beaumont) Live at Five News Report. Television Interview on Paget's Disease. Dec. 12, 1991
25. What's New in Diabetes Mellitus? Nursing Grand Rounds, St. Elizabeth Hospital. Dec. 1991.
26. Osteoporosis. Cavalry Baptist Church Bazaar. Beaumont, Texas. Jan 10, 11 1992.
27. Diabetes Management. Home Health Care Nurses, St Elizabeth Hospital. Jan. 1992.
28. Diabetes in the Critically Ill. Nursing Grand Rounds, St. Elizabeth Hospital. Feb, 1992.
29. Osteoporosis. NAACOG, St Elizabeth Hospital. June 1992.
30. Clinical Perspectives on Blood Lipids. Orlando, Florida. Aug. 1992
31. Diabetes Mellitus. Seminole County Chamber Business Show/Florida Hospital. Altamonte, Fl. Aug. 1992.
32. Diabetes Therapy for the 90's. St. Mary's Hospital / Welborn Hospital in Evansville, IN. July 1993.
33. Diabetes Mellitus. Diabetes Expo '93: Celebrate Education. Maitland, Fl. Nov. 1993.
34. Thyroid Nodule. Grand Rounds Health Central Hospital, Ocoee, Fl. July 1994.
35. Moving Forward with Control. Diabetes Support Centers Columbia Park Medical Center. March 1994.
36. "Hágase Responsable de su Salud: La Diabetes y Usted" Florida Hospital East Orlando. May 1994.
37. Update on Diabetes. Yearly Pan-American Medical Association Meeting, Longboat Key, Fl. Sept. 1994.
38. Can Diabetes be Prevented? Dine with the Docs, Osceola Regional Hospital. Jan. 1995.
39. Diabetes Treatments. Diabetes Support Group Meeting Health Central Hospital, Ocoee, Fl. June 1995.
40. Updates on Diabetes. Diabetes Expo '95. Maitland, Fl. Nov. 1995.
41. Diabetic Ketoacidosis. Grand rounds at Sand Lake Hospital, Orlando, Fl. July 1996.
42. Update on Diabetes. Yearly Pan-American Medical Association Meeting, Longboat Key, Fl. Sept. 1997.
43. Insulin Use In the Outpatient Setting. Dinner Discussion. Orlando, Fl. Nov. 2004.
44. Basal Insulin. Dinner Discussion. Orlando, Fl. Jan. 2005.
45. Intensive Insulin Use in Hospitalized Patients. Orlando Regional Medical Center-Lucerne. Orlando, FL May 2005.
46. Intensive Insulin Use in Hospitalized Patients. Health Central Hospital. Ocoee, Fl. May 2005.
47. Insulin Use in Hospitals. Dinner Discussion for Hospitalists. Orlando, Fl. Aug. 2005.
48. Use of Basal Insulin in the Outpatient Setting. Dinner Discussion for primary care specialists. Orlando, FL Aug. 2005.
49. The Use of Basal Insulin in Type 2 Diabetes. Dinner Presentation, Orlando, Fl. Oct. 2005.
50. Insulin Use in the Outpatient Setting. Orlando Regional Med. Center, Orlando, Fl. April 2006.
51. The Use of Basal Insulins. Dinner Presentation for Primary Care Physicians. Orlando, Fl. Feb. 2007
52. Insulin Use in Type 2 Diabetes Mellitus. Dinner Presentation, Winter Park, Fl. June, 2007
53. Lantus Insulin in Type 2 Diabetes. Dinner Presentation. Winter Park, Fl. Sept. 2007.
54. Diabetes Case Histories. Dinner Presentation. Winter Park, Fl. Jan. 2008
55. Insulin Use in Type 2 Diabetes. Dinner Presentation. Winter Park, Fl. June 2008
56. Managed Care Perspectives on Diabetes Management. Orlando Fl. Sept. 2008
59. Guest speaker for WMEUS Radio Station to discuss Diabetes Mellitus on 4/4/09 on the Weekly show "Yo Soy Latino".
60. Basal and Prandial Insulin use in the Hospitalized Patient. Dinner Presentation. Winter Park May 5, 2010.
61. Insulin use in Hospitalized Patients: A Basal/ Prandial Approach. Orlando, Fl. June 10, 2010

62. Use of Basal and Prandial Insulin. Apopka, Fl. July 28, 2010.
63. Basal and Prandial Insulin use in the ICU setting. Winter Park, Fl. September 16, 2010.
64. Basal and Prandial Insulin use in the Hospitalized Patient. Orlando, Fl. October, 28, 2010.
65. Glycemic Control for Inpatients: Multimodal Approach. Orlando, Fl. April 6, 2011.
66. Basal insulin use for the Outpatient Type 2 Diabetics: a Rational Approach. Orlando, Fl. June 15, 2011.
67. Effective Management of Hyperglycemia in Hospitalized Patients with Type 2 Diabetes Winter Park, Fl. February 28, 2012
68. Rapid Acting Insulin Management Program: A Call to Action for Primary Care Practitioners Gainesville, Fl. November 14, 2012.
69. Improving Glycemic Control in Type 2 Diabetes: A Stepwise Approach to Initiating and Intensifying Insulin Treatment. Winter Garden, Fl. October 10, 2013
70. Evolving Treatment Aspects in Type 2 Diabetes Management: A Comprehensive Approach To Help Your Patients Achieve Glycemic Control. Ocala, Fl. October 24, 2013

ABSTRACTS/PUBLICATIONS

1. Abnormal Vitamin D Metabolism in Patients with Lymphoma. J. Mandry, M. Browne, B. Hollis, C. Eil. Presented at the 12th Annual Meeting of the American Society for Bone and Mineral Research, Aug. 1990 Atlanta, Georgia.
2. Hyperphosphatemia in Multiple Myeloma due to a Phosphate Binding Immunoglobulin. J. Mandry, M. Posner, J.R.Tucci, C. Eil. Presented at the Annual Scientific Meeting of the American College of Physicians –Rhode Island Chapter, March 1990. Published in the Cancer Journal Vol. 68, No. 5, Sept. 1, 1991.
3. Familial Non-MEN Medullary Thyroid Carcinoma, a Poorly Recognized Clinical Syndrome. J. Mandry, MD, I. Jackson, MD. Presented at the Annual Scientific Meeting of the American College of Physicians - Rhode Island Chapter, 1991.
4. Apparent Glucocorticoid Resistance due to Altered Prednisolone Pharmacokinetics in an Adolescent with Lupus Vasculitis. Presented at the 73rd Annual Endocrine Society Meeting, June 1991.

CLINICAL RESEARCH

1. Advanced Diabetes Treatment Centers. MAT Research, Winter Park, Fl. 2002-2008
2. Clinical Trials Management Research. 2008
3. INCB 13739-202 2ble blind, dose ranging, placebo controlled randomized study to evaluate the safety and efficacy of INCB013739 plus metformin compared to metformin alone on glycemic control in Type 2 DM. Incyte Corporation. 2008. Sub-Investigator
4. Takeda. SYR 322_303 Multicenter randomized, 2ble blind study to evaluate the efficacy and safety of alogliptin compared to glipizide in elderly subjects with Type 2 DM. 2008. Sub-Investigator
5. Phase III, 3 arm, randomized, 2ble blind, placebo controlled multicenter study to investigate the impact of Diamyd in the progression of DM in newly diagnosed patients with Type 1. 2008. Sub-investigator
6. Randomized, 2ble blind, 2-arm Parallel-group, 3 year, Multicenter Study to determine the Efficacy, safety, and tolerability of titrated doses of JNJ-28431754 versus titrated doses of glimepiride in the treatment of subjects with Type 2 DM not optimally controlled on Metformin. 2008. Sub-Investigator
7. Randomized, 2ble blind, Placebo controlled, Parallel-Group Study of the Efficacy and Safety of Welchol as Monotherapy for Type 2 DM. 2008. Sub-Investigator
8. Glumetza Observational Study. Add-on to SU or metformin + SU combo therapy. Project # 11954. Roche protocol RO5073031. Completed 2008 Sub-Investigator
9. 6 month, multicenter, randomized, open label, parallel group study comparing the efficacy and safety of a new formulation of insulin glargine and Lantus both plus mealtime insulin in patients with type-2

- diabetes with a 6 month safety extension period. Completed 2013. Principal Investigator
10. 6 month, multicenter, randomized, open-label, parallel-group study comparing the efficacy and safety of a new formulation of insulin glargine and Lantus both in combination with oral antihyperglycemic drugs in patients with type 2 diabetes mellitus with a 6 month safety extension period. Completed 2013. Principal Investigator.
 11. An ACromegaly, open-label, multiCenter, Safety monitoring program for treating patients with SOM233 (pasireotide) LAR who have need to receive medical therapy (ACCESS). Completed 2015. Principal Investigator.
 12. A randomize, 30 week, active-controlled, open-label, 3-treatment arm, parallel-group multicenter study comparing the efficacy and safety of insulin Glargine/lixisenatide fixed ratio combination to insulin Glargine alone and to lixisenatide alone on top of metformin in patients with type 2 diabetes mellitus (T2DM). Completed 2014. Principal Investigator.
 13. A randomized, 30-week, active-controlled, open-label, 2 treatment-arm, parallel-group, multicenter study comparing the efficacy and safety of the insulin Glargine/lixisenatide fixed ratio combination to insulin Glargine with or without metformin in patients with T2DM. Completed 2014. Principal Investigator.
 14. A randomized, open-label-2-arm parallel-group, multicenter, 26-week study assessing the safety and efficacy of HOE901-U300 versus Lantus in older patients with type 2 diabetes inadequately controlled on antidiabetic regimens either including insulin, or basal insulin as their only insulin. Completed 2016, Principal Investigator.
 15. Six-month, Randomized, Open-label, Parallel-group Comparison of the Insulin Analog SAR342434 to Humalog in Adult Patients with Type 2 Diabetes Mellitus also using Insulin Glargine. Completed 2016, Principal Investigator.
 16. A randomized, open-label, parallel group real world pragmatic trial to assess the clinical and health outcomes of Toujeo® compared to commercially available basal insulins for initiation of therapy in insulin naïve patients with uncontrolled type 2 diabetes mellitus. Completed 2018. Principal Investigator.
 17. Randomized, Open-Label, Parallel Group Study to Evaluate the Efficacy and Safety of Alirocumab versus Usual Care in Patients with Type 2 Diabetes and Mixed Dyslipidemia at High Cardiovascular Risk with Non-HDL-C Not Adequately Controlled with Maximally Tolerated Statin Therapy. Completed 2017. Principal Investigator.
 18. A 24-week, Multicenter, Randomized, Open-label, Parallel-group Study Comparing the Efficacy and Safety of Toujeo® and Tresiba® in Insulin-Naive Patients with Type 2 Diabetes Mellitus not Adequately Controlled with Oral Antidiabetic Drug(s) ± GLP-1 receptor agonist” (“Protocol”). Completed 2017.. Principal Investigator.
 19. A Randomized, Active-Controlled, Parallel Group, 16-Week Open Label Study Comparing the Efficacy and Safety of the Morning Injection of Toujeo (Insulin Glargine-U300) Versus Lantus in Patients with Type 1 Diabetes Mellitus. Completed 2017. Principal Investigator.
 20. Six-month, Randomized, Open-label, Parallel-group Comparison of SAR341402 to NovoLog®/NovoRapid® in Adult Patients With Diabetes Mellitus Also Using Insulin Glargine, with a 6-month Safety Extension Period. Completed 2018. Principal Investigator.
 21. A Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Efficacy and Safety of Sotagliflozin Added to a Sulfonylurea alone or in combination with Metformin in Patients with Type 2 Diabetes Who Have Inadequate Glycemic Control on a Sulfonylurea Alone or with Metformin Completed 2019 Principal Investigator.
 22. A Randomized, Double-blind, Placebo- controlled, 3-arm, Parallel-group, 52-week Multicenter Study to Evaluate the Efficacy and Safety of Sotagliflozin in Patients with Type 2 Diabetes Mellitus and Severe Renal Impairment who have Inadequate Glycemic Control. Completed 2019 Principal Investigator.
 23. A Randomized, Double-blind, Placebo-controlled, 3-arm, Parallel-group, 52-week Multicenter Study to Evaluate the Efficacy and Safety of Sotagliflozin in Patients with Type 2 Diabetes Mellitus and Moderate Renal Impairment who have Inadequate Completed 2019, Principal Investigator.

24. A 52-week Randomized, Double-blind, Double-dummy, Active and Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Efficacy and Safety of Sotagliflozin compared to Glimepiride or Placebo Added to Metformin in Patients with Type 2 Diabetes who have Inadequate Glycemic Control with Metformin Monotherapy. Completed 2019 Principal Investigator.
25. A Randomized, Placebo-Controlled, Double-Blind, Multicenter, Phase 2 Study to Assess Safety, Tolerability, and Renal Effects of TMX-049 in Subjects with Type 2 Diabetes and Albuminuria. Completed 2019. Principal Investigator.
26. TRAVERSE Study. Testosterone Replacement Therapy for Assessment of long-term Vascular Events and Efficacy Response in Hypogonadal Men. Sponsor AbbVie. Aug 2018, ongoing. Principal Investigator.
27. A 26-week Randomized, Double-blind, Controlled, Parallel-group, Multicenter Study to Evaluate the Efficacy and Safety of Sotagliflozin compared to Empagliflozin, and Placebo in Patients with Type 2 Diabetes Who Have Inadequate Glycemic Control on Dipeptidyl Peptidase 4 Inhibitor (DPP-4) With or Without Metformin. Completed 2019, Principal Investigator.
28. Phase3B/4 Randomized Safety Endpoint Study of 2 Doses of Tofacitinib in comparison to a Tumor Necrosis Factor (TNF) Inhibitor in Subject with Rheumatoid Arthritis. Pfizer. Completed 2019. Principal Investigator.
29. Efficacy and Safety of Sotagliflozin Versus Placebo in Subjects With Type 2 Diabetes Mellitus Who Have Inadequate Glycemic Control While Taking Insulin Alone or With Other Oral Antidiabetic Agents (SOTA-INS) Completed 2019. Principal Investigator.
30. LIXILAN-D (DIVERSITY): A 26-week randomized, open-label, active-controlled, 2-treatment arm, parallel-group multi-center study, comparing the Efficacy and Safety of Soliqua Versus Lantus in Ethnically/Racially Diverse Patients With Type 2 Diabetes Mellitus Inadequately Controlled on Basal Insulin and Oral Antidiabetic Agents (LixiLan-D) Dec 2018 completed Principal Investigator.
31. Randomized, Open label, Parallel-group Study Comparing the Pharmacokinetics and Immunogenicity of Alternating Use of SAR341402 and NovoLog® versus Continuous Use of NovoLog in Patients with Type 1 Diabetes Mellitus also Using Insulin Glargine. Mar 2020. Principal Investigator.
32. A phase 3, multicenter, randomized, double-blind, placebo-controlled, active reference (adalimumab) study evaluating the efficacy and safety of bimekizumab in the treatment of subjects with active psoriatic arthritis. Jan 2021, Principal Investigator.
33. PROMINENT prominent pemafibrate to reduce cardiovascular outcomes by reducing triglycerides in patients with diabetes. Ongoing started 2017, Principal Investigator.
34. SAPPHIRE; A Phase 2b, Multicentre, Randomised, Double-blind, Placebo-controlled Study of Verinurad and Allopurinol in Patients with Chronic Kidney Disease and Hyperuricaemia, Jan 2022, Principal Investigator.
35. A Randomized, Non-Inferiority, Phase 3, Open-Label, Multicenter Study to Evaluate the Efficacy and Safety of Abaloparatide-sMTS for the Treatment of Postmenopausal Women with Osteoporosis (Wearable Study) Jan 2022, Principal Investigator
36. AbbVie / “24-Hour Ambulatory Blood Pressure Monitoring Study in Hypogonadal Men Receiving Testosterone Replacement Therapy” Mar 2022. Principal Investigator.
37. ANJ900D3501: A randomized, multicenter, double-blind, parallel-group, placebo-and comparator-controlled study to compare the glycemic effects, safety, and tolerability of metformin hydrochloride delayed-release tablets in patients with type 2 diabetes mellitus with varying renal function from normal up to CKD3B Sep, 2021 ongoing. Principal Investigator.
38. D9488C00001: A Phase 3, International, Randomised, Double-blind, Placebo-controlled Study to Evaluate the Effect of Sodium Zirconium Cyclosilicate on Chronic Kidney Disease (CKD) Progression in Participants with CKD and Hyperkalaemia or at Risk of Hyperkalaemia Oct 2021 ongoing.
39. CSL346_2001: A Phase 2a, Double-blind, Randomized, Placebo-controlled, Proof of Concept Study of Vascular Endothelial Growth Factor (VEGF)-B Blockade with the Monoclonal Antibody CSL346 in Subjects with Diabetic Kidney Disease, Mar 2021, ongoing, Principal Investigator.

40. I8F-MC-GPHL: Efficacy and Safety of Tirzepatide Once Weekly versus Placebo in Participants with Type 2 Diabetes Who Have Obesity or Are Overweight with Weight-Related Comorbidities (SURMOUNT-2) ongoing May 2021, Principal Investigator.

Kathy Mandry, MS, RD, LD/N.....Site administrator

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Education/Employment

1. University of Kentucky, Lexington, KY. Bachelors of Science General Dietetics. 1984.
2. Cardinal Hill Hospital, Lexington KY. Dietetic Technician. 1984-1986.
3. St. Joseph Hospital, Lexington KY. RD Qualifying Experience. 1987.
4. Department of Endocrine and Metabolism Veterans Hospital, Dr. James Anderson, MD, research and development, Lexington, KY. Assistant to research dietitian. 1987.
5. University of Kentucky, Lexington, KY. Masters of Science Specialty in Clinical Nutrition. 1988.
6. St. Joseph Hospital, Lexington KY. Dietetic Technician. 1987-1988.
7. Roger Williams Hospital, Providence, RI. Clinical Dietitian. 1988 -1989.
8. Rhode Island Hospital, Providence RI. Nutrition Support Dietitian. 1989-1990.
9. PAHCF Inc, Providence RI. Diabetes Outpatient Educator. 1989-1990.
10. Visiting Nurses Association, Providence, RI. Consulting Dietitian. 1989-1991.
11. Veteran's Administration Hospital, Providence, RI. Clinical Dietitian. 1989-1991.
12. Valencia College, Orlando FL. Adjunct Nutrition Professor. 2010 to 2013.
13. Animas Corporation, a Johnson and Johnson company, West Chester, PA. Insulin pump educator. 2011 to 2012.
14. West Orange Endocrinology, P.A., 2011 to present.

Certifying Examinations

1. Commission of Dietetic Registration, credentialing agency for Academy of Nutrition and Dietetics. Registered Dietitian. 1988 to current.
2. Commission of Dietetic Registration, credentialing agency for Academy of Nutrition and Dietetics, Nutrition Support Dietitian Certification. 1989.
3. Barnett Education Services, Webinar. CRA and CRC beginner Program. 2012.
4. NIH Office of Extramural Research certificate "Protecting Human Research Patients". 2012.
5. Academy of Nutrition and Dietetics, certificate of membership. 1990-present.
6. Florida Academy of Nutrition and Dietetics, certificate of membership, 2013-present.
7. IATA certified Mayo Clinic.
8. Good Clinical Practices, Brookwood Institute, December 2016

Maria Ines Marulanda MD..... Sub-Investigator Clinical Research Director

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EDUCATION

1. Carabobo University-Angel Larralde Hospital -Valencia, Venezuela
2. Internal Medicine Doctor - December 1990
3. Carabobo University - Faculty of Health Sciences Valencia, Venezuela
4. Physician and Surgeon Degree July 1984
5. Honors: Medical Student Association President (1983-1984)

INTERNSHIP AND RESIDENCY

1. Angel Larralde Hospital - Valencia, Venezuela
2. Internal Medicine Residence - 1987-1990
3. Honors: Chief Resident
4. Guerra Méndez Medical Center - Valencia, Venezuela
5. Intensive Care Unit Resident - 1987-1990
6. Adolfo Prince Lara Hospital - Pto. Cabello, Venezuela
7. Rotating Residence - 1984-1987

OTHER PROFESSIONAL TRAINING

1. Fundation Santa Fé Hospital - Bogotá, Colombia
2. Course advanced nutritional support - 2006
3. Our Lady of the Lake Regional Medical Center - Baton Rouge, Louisiana
4. Geriatrics Training - 1993
5. Registered Medical Assistant - RMA - Miami Fl 2015
Registered Electrocardiography Technician – EKG - Miami Fl 2015
Registered Phlebotomy Technician - RPT - Miami Fl 2015

EXPERIENCE

1. Guerra Méndez Medical Center - Valencia, Venezuela
2. Staff Internal Medicine Physician - 1991 – 2015
3. Medical Director 2014-2015
4. Responsible for the weekly care of 20 patients in the Emergency room and inpatients
5. Private Practice Office attended around 20 patients daily
6. President of the Medical Society 2004-2008
7. Clinical Research Director, West Orange Endocrinology, PA June 2016-now

TEACHING

1. Carabobo University- Valencia, Venezuela
2. Associate Professor of Internal Medicine Residency Program - 1992 –2015
3. TNT (Total Nutrition Therapy) Advance Course - Venezuela
4. National Coordinator - 2006 - 2015
5. TNT-MG (Total Nutrition Therapy in Geriatrics - Venezuela
6. National Coordinator - 2012 – 2015
7. PROFESSIONAL MEMBERSHIPS
8. Venezuelan Society of Internal Medicine (SVMI), President 2013- 2015
9. American College of Physicians (ACP), Fellow since 2002

10. American College of Cardiology (ACC), Fellow since 2010
11. European Society of Cardiology (ESC), Fellow since 2011
12. American Heart Association (AHA), Member since 2005
13. Vascular Biology Working Group (VBWG), Member since 2010
14. Latin-American Society of Internal Medicine (SOLAMI), Member since 2000
15. American Society of Parenteral and Enteral Nutrition (ASPEN), Member since 2000
16. European Society of Parenteral and Enteral Nutrition (ESPEN), Member since 2000
17. Latin-American Federation of Parenteral and Enteral Nutrition (FELAMPE), Member since 2000

PUBLICATIONS

1. Marulanda, Maria I. , Nieto, R., et al. Promoting a Healthy Lifestyle in Venezuela. *Medicina Interna* 2015, 31: (3) 82-111
2. Nieto, R., Marulanda Maria I., et al. Venezuelan Study of Cardiometabolic Risk Factors (EVESCAN I). *Medicina Interna* 2015, 31: (2) 102-111
3. Nieto, R., Hamdy, O., Marante , D., Marulanda, MI. Transcultural Nutrition Diabetes Algorithm (tDNA) Venezuelan Application. *Nutrients* 2014, 6, 1333-1363
4. Marulanda, MI ;et al International Diabetes Management Practices Study in Venezuela (IDMPS- Venezuela – Wave 2). *Medicina Interna* 2013,28(4):2014-2023
5. Marulanda, MI Preoperative Nutritional Assesment in Perioperative Medical Evaluation
6. Marulanda,MI Critical analysis of the literature on research problem in Clinical Research and Internal Medicine
7. Marulanda,MI Atherosclerosis Silent Enemy in Cardiovascular Disease, *Internal Medicine* Updated,2008,1:12-17
8. Marulanda,MI Dislipidemy in Metabolic Syndrome in *Internal Medicine* Updated 2009,4:16-19
9. Marulanda,MI Pulmonary Complications of Chickenpox *Journal of Clinical I (I):* 30-36, 1988.
10. Marulanda, MI Monoclonal gammopathy IGM: Macroglobulinemia Waldemstrom *Journal of Clinical I (I):* 50-53, 1988.
11. Marulanda,MI Study of Infectious Diseases at the University Hospital Angel Larralde *Journal of Clinical I (2):* 20-25, 1988
12. Marulanda,MI Preliminary Experience imipenem-Cilastatin University Hospital Angel Larralde. *Medical Isabelica*, 11: 269-272, 1988
13. Marulanda, MI Clinical and Therapeutic Efficacy of Cefoperazone in Severe Infections" *Venezuelan Archives of Pharmacology* 7: 197-201, 1988.
14. Marulanda,MI Bacterial Resistance in the Angel Larralde Hospital Publications Dept. *Internal Medicine*, 1988.
15. Marulanda, MI , Stroke in young people , *Journal of Clinical* 2 (1): 39-44, 1989.
16. Marulanda, MI Infective endocarditis: 10 years of experience at the Angel Larralde University Hospital *Internal Medicine* 5: 154 -159, 1989.
17. Marulanda,MI Extrahospitalarias Infections in Elderly. *Journal of Clinical* 3 (1) .: 38-42, 1989.
18. Marulanda MI Guillain-Barre Syndrome, Therapeutic Clinical Experience, *Venezuelan Journal of Neurology and Neurosurgery*, 4: 89 81-. 1990.
19. Marulanda, MI Infection of Central Nervous System Tuberculosis, *Images* 2: 1-9, 1991.
20. Marulanda, MI Subarachnoid Hemorrhage: Analysis of 52 cases in a General Hospital *Venezuelan Journal of Neurology and Neurosurgery*, 5: 33-40, 1991.
21. Marulanda, MI Evaluation of the Patient with Syncope *Internal Medicine* 10 (3): 121-122, 1994.
22. Marulanda, MI Evaluation of the Patient with Headache *Internal Medicine*, 10 (3): 123, 1994.
23. Marulanda, MI Thoracic Pain: Not Always a heart attack. *Medicine Today* sixth anniversary, in August 2000
24. Marulanda ,MI Utility of Subjective Global Assessment in nutritional assessment inpatient . *Readings on Nutrition* Vol 7: 67-74

25. Marulanda, MI Definition of therapeutic goals; special conditions: dyslipidemia in women, children and adolescents; special condition: AIDS patients; Niacin. in Booklet of diagnostic and treatment of dyslipidemia, 2011 Atha Comunicação e Editora Ltda, CEP 04044-000 S.P.
26. Diabetes and Infection in Diabetes Mellitus pag 267-285, Edit Disinlime, 1998, Valencia
27. Board Member : Venezuelan Task Force of Lipids I, II and III,
28. Board Member : Venezuelan Task Force of Venous Tromboembolic Disease I,II,III and IV, Latinoamerican Task Force of Dislipidemias
29. Board Member: Venezuelan Uric Acid Consensus 2016
30. Venezuelan Task Force of Neuropatic Pain
31. Editor Chief of Up to Date in Internal Medicine
32. Editorial Comittee Member of Internal Medicine

RESEARCH

Principal Investigator:

1. JUPITER, CLAFF237B2224, AGHATA, IDMPS, CLAFF, ACELERATE, ACCESS, PALLAS, ATMOSPHERE, EPICOR, CPSPP100AVEN01, CLAF 237A23104, EVESCAM and others Clinical Research Director
2. Randomized, Open-Label, Parallel Group Study to Evaluate the Efficacy and Safety of Alirocumab versus Usual Care in Patients with Type 2 Diabetes and Mixed Dyslipidemia at High Cardiovascular Risk with Non-HDL-C Not Adequately Controlled with Maximally Tolerated Statin Therapy. Completed 2017
3. A 24-week, Multicenter, Randomized, Open-label, Parallel-group Study Comparing the Efficacy and Safety of Toujeo® and Tresiba® in Insulin-Naive Patients with Type 2 Diabetes Mellitus not Adequately Controlled with Oral Antidiabetic Drug(s) ± GLP-1 receptor agonist” (“Protocol”). Completed 2017.
4. A Randomized, Active-Controlled, Parallel Group, 16-Week Open Label Study Comparing the Efficacy and Safety of the Morning Injection of Toujeo (Insulin Glargine-U300) Versus Lantus in Patients with Type 1 Diabetes Mellitus. Completed 2017.
5. SOTA-SU (EFC14835): A Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Efficacy and Safety of Sotagliflozin Added to a Sulfonylurea alone or in combination with Metformin in Patients with Type 2 Diabetes Who Have Inadequate Glycemic Control on a Sulfonylurea Alone or with Metformin
6. GEMELLI (EFC15081.): Six-month, Randomized, Open-label, Parallel-group Comparison of SAR341402 to NovoLog /NovoRapid in Adult Patients With Diabetes Mellitus Also Using Insulin Glargine, with a 6-month Safety Extension Period
7. SOTA-CKD3 (EFC14837: A Randomized, Double-blind, Placebo-controlled, 3-arm, Parallel-group, 52-week Multicenter Study to Evaluate the Efficacy and Safety of Sotagliflozin in Patients with Type 2 Diabetes Mellitus and Moderate Renal Impairment who have Inadequate Glycemic Control
8. SOTA-CKD4 (EFC15166): A Randomized, Double-blind, Placebo-controlled, 3-arm, Parallel-group, 52-week Multicenter Study to Evaluate the Efficacy and Safety of Sotagliflozin in Patients with Type 2 Diabetes Mellitus and Severe Renal Impairment who have Inadequate Glycemic Control
10. SOTA-EMPA: (EFC14867): A 26-week Randomized, Double-blind, Controlled, Parallel-group, Multicenter Study to Evaluate the Efficacy and Safety of Sotagliflozin compared to Empagliflozin, and Placebo in Patients with Type 2 Diabetes Who Have Inadequate Glycemic Control on Dipeptidyl Peptidase 4 Inhibitor (DPP4(i)) With or Without Metformin
11. SOTA-GLIM (EFC14838): A 52-week Randomized, Double-blind, Double dummy, Active and Placebo-controlled, Parallel group, Multicenter Study to Evaluate the Efficacy and Safety of Sotagliflozin compared to Glimepiride or Placebo Added to Metformin in Patients with Type 2 Diabetes who have Inadequate Glycemic Control with Metformin Monotherapy

12. DIVERSITY (LPS14860): A 26-week randomized, open-label, active-controlled, 2-treatment arm, parallel-group multi-center study, comparing the efficacy and safety of Soliqua™100/33 versus Lantus® in ethnically/racially diverse patients with type 2 diabetes mellitus inadequately controlled on basal insulin and oral antidiabetic agents with a 26-week extension period.
13. Protocol: TMX-049DN-201A Randomized, Placebo-Controlled, Double-Blind, Multicenter, Phase 2 Study to Assess Safety, Tolerability, and Renal Effects of TMX-049 in Subjects with Type 2 Diabetes and Albuminuria.
14. Efficacy and Safety of Sotagliflozin Versus Placebo in Subjects With Type 2 Diabetes Mellitus Who Have Inadequate Glycemic Control While Taking Insulin Alone or With Other Oral Antidiabetic Agents (SOTA-INS)
15. GEMELLI EFC15178: A Randomized, Open label, Parallel-group Study Comparing the Pharmacokinetics and Immunogenicity of Alternating Use of SAR341402 and NovoLog® versus Continuous Use of NovoLog in Patients with Type 1 Diabetes Mellitus also Using Insulin Glargine.
16. M16-100: Testosterone Replacement Therapy for Assessment of long-term Vascular Events and Efficacy Response in Hypogonadal Men.
17. TRAVERSE Study. Testosterone Replacement Therapy for Assessment of long-term Vascular Events and Efficacy Response in Hypogonadal Men. Sponsor AbbVie. Aug 2018
18. PROMINENT (K877-302): Pemaflibrate to reduce cardiovascular outcomes by reducing triglycerides in patients with diabetes.
19. D5495C00002: A Phase 2b, Multicenter, Randomized, Double-blind, Placebo-controlled Study of Verinurad and Allopurinol in Patients with Chronic Kidney Disease and Hyperuricemia
20. BA058-05-021: A Randomized, Non-Inferiority, Phase 3, Open-Label, Multicenter Study to Evaluate the Efficacy and Safety of Abaloparatide-sMTS for the Treatment of Postmenopausal Women with Osteoporosis (Wearable Study)
21. ANJ900D3501: A randomized, multicenter, double-blind, parallel-group, placebo-and comparator-controlled study to compare the glycemic effects, safety, and tolerability of metformin hydrochloride delayed-release tablets in patients with type 2 diabetes mellitus with varying renal function from normal up to CKD3B
22. D9488C00001: A Phase 3, International, Randomised, Double-blind, Placebo-controlled Study to Evaluate the Effect of Sodium Zirconium Cyclosilicate on Chronic Kidney Disease (CKD) Progression in Participants with CKD and Hyperkalaemia or at Risk of Hyperkalaemia
23. CSL346_2001: A Phase 2a, Double-blind, Randomized, Placebo-controlled, Proof of Concept Study of Vascular Endothelial Growth Factor (VEGF)-B Blockade with the Monoclonal Antibody CSL346 in Subjects with Diabetic Kidney Disease
24. I8F-MC-GPHL: Efficacy and Safety of Tirzepatide Once Weekly versus Placebo in Participants with Type 2 Diabetes Who Have Obesity or Are Overweight with Weight-Related Comorbidities (SURMOUNT-2)
25. Randomized, Open-Label, Parallel Group Study to Evaluate the Efficacy and Safety of Alirocumab versus Usual Care in Patients with Type 2 Diabetes and Mixed Dyslipidemia at High Cardiovascular Risk with Non-HDL-C Not Adequately Controlled with Maximally Tolerated Statin Therapy. Completed 2017
26. A 24-week, Multicenter, Randomized, Open-label, Parallel-group Study Comparing the Efficacy and Safety of Toujeo® and Tresiba® in Insulin-Naive Patients with Type 2 Diabetes Mellitus not Adequately Controlled with Oral Antidiabetic Drug(s) ± GLP-1 receptor agonist” (“Protocol”). Completed 2017.
27. A Randomized, Active-Controlled, Parallel Group, 16-Week Open Label Study Comparing the Efficacy and Safety of the Morning Injection of Toujeo (Insulin Glargine-U300) Versus Lantus in Patients with Type 1 Diabetes Mellitus. Completed 2017.
28. Six-month, Randomized, Open-label, Parallel-group Comparison of SAR341402 to NovoLog®/NovoRapid® in Adult Patients With Diabetes Mellitus Also Using Insulin Glargine, with a 6-month Safety Extension Period. Ongoing. Sub-Investigator.
29. A Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Efficacy and Safety of Sotagliflozin Added to a Sulfonylurea alone or in combination with Metformin in

Patients with Type 2 Diabetes Who Have Inadequate Glycemic Control on a Sulfonylurea Alone or with Metformin Ongoing. Sub- Investigator.

LECTURES

1. Numerous visiting professorships and lectures in National Congress
2. Numerous Lectures in International Congress: World Congress of Internal Medicine, Latinoamerican Congress of Internal Medicine, Latinoamerican Congress of Parenteral and Enteral Nutrition Federation, International Congress of Internal Medicine, Argentina Congress of Internal Medicine, Peruvian Congress of Internal Medicine and Cardiology, Paraguay Congress of Internal Medicine, Colombian Congress of Internal Medicine, Chilean Congress of Internal Medicina, Dominican Congress of Internal Medicina
3. AWARDS
4. Volunteerism and Community Service award by American College of Physician Venezuelan Chapter, Venezuela, 2007
5. Volunteerism and Community Service award by American College of Physician Venezuelan Chapter, Venezuela, 2014
6. Order of Academic Merit “Dr Jose Solanes” awarded by the College of Physicians in Carabobo State Venezuela, 2002

Ineska Freire MD.....Clinical Research Coordinator

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PROFESSIONAL ASSOCIATIONS

1. MD Registration number (Venezuela): MSDS: 72864
2. Number of college of physicians at Carabobo’s State: 9039
3. American College of Physicians (ACP) # 01278950

EDUCATION

1. CARABOBO STATE UNIVERSITY – AT ANGEL LARRALDE’S UNIVERSITARY HOSPITAL MASTER OF SCIENCE DEGREE. SPECIALIST IN INTERNAL MEDICINE 2009-2011. Valencia – Venezuela. Academic grade point Average: 17.53 = A-
2. THE CARABOBO STATE UNIVERSITY BACHELOR OF SCIENCE DEGREE OF MEDICAL SURGEON/PHYSICIAN 2002-2007. Valencia – Venezuela. Academic grade point Average: 16,76 = B+

ACADEMIC COURSE TRAINING

1. BLS FOR HEALTH CARE PROVIDERS American Heart Association, February 2016

2. REGISTERED MEDICAL ASSISTANT – RMA Registry Number: 20150421569 Florida Registry of Medical Assistants, April 2015
3. REGISTERED PHLEBOTOMY TECHNICIAN – RPT Registry Number: 20150421570 Florida Registry of Medical Assistants, April 2015
4. REGISTERED ELECTROCARDIOGRAPHY TECHNICIAN – EKG Registry Number: 20150421571 Florida Registry of Medical Assistants, April 2015
5. ADVANCED CARDIAC LIFE SUPPORT (ACLS), 2013
6. TNT (TOTAL NUTRITIONAL THERAPY). SVNPE – FELANPE Abbott Nutrition. Valencia – Venezuela. October 2008
7. TRAINING: GOOD CLINICAL PRACTICE AND CLINICAL RESEARCH GENERALITIES
8. RPS Colombia LTDA. Caracas-Venezuela. April 2012.
9. TNT - MG (TOTAL NUTRITIONAL THERAPY) GERIATRIC. SVNPE - EUGMS – ALMA. Abbott Nutrition. Valencia – Venezuela. April, 2013
10. EXERCISE IS MEDICINE. Caracas – Venezuela. September 2013
11. INTERNATIONAL INTENSIVE THEORETICAL AND PRACTICAL COURSE OF METABOLIC AND NUTRITIONAL SUPPORT. Fundación Santa Fe de Bogotá - FELAMPE. Bogotá, October, 2013.

HONORS AND AWARDS

“Dr. Miguel Pérez Carreño’s Award” 2007 - Honourable mention
 Paper work titled: "Assessment of Cardiovascular Risk in Patients with Chronic Renal Failure on Hemodialysis."

RESEARCH PARTICIPATION IN CLINICAL TRIALS

1. “EPICOR. (long-term follow-up of antithrombotic management Patterns In acute CORonary syndrome patients) study: rationale, design, and baseline characteristics.”Co-investigator
2. CLAF237B2224 “Efficacy and Long-Term Safety of Vildagliptin as Add-on Therapy to Metformin in Patients With Type 2 Diabetes.”Co-investigator
3. BIMAP: “Profenid-BI® in daily practice Management of Acute episodes of Pain in acute and chronic conditions.” Co-investigator.
4. ATMOSPHERE: “Direct renin inhibition in addition to or as an alternative to angiotensin converting enzyme inhibition in patients with chronic systolic heart failure: rationale and design of the Aliskiren Trial to Minimize OutcomeS in Patients with HEart failuRE study. Study Coordinator

WORK EXPERIENCE

1. RESPIRATORY THERAPY UNIT. CENTRO MÉDICO GUERRA MÉNDEZ
 February –October, 2005. Valencia – Venezuela
2. RURAL PHYSICIAN. AMBULATORIO URBANO TIPO II MARIARA – INSALUD,
 VENEZUELA January – December. 2008. Mariara – Venezuela.
3. INTERNAL MEDICINE RESIDENCE AT ANGEL LARRALDE’S UNIVERSITARY HOSPITAL
 – CHIEF RESIDENT January 2009 - December 2011 - IVSS. Valencia – Venezuela.
4. EMERGENCY PHYSICIAN. CENTRO MÉDICO GUERRA MÉNDEZ March, 2012 – August, 2013.
 Valencia –Venezuela.
5. STAFF PHYSICIAN OF INTERNAL MEDICINE DEPARTMENT. CENTRO MÉDICO GUERRA
 MÉNDEZ. Responsible for the weekly care of 20 patients in the emergency room and hospital
 inpatients. September, 2013 – February 2015. Valencia – Venezuela
6. STAFF PHYSICIAN OF SERVIMEDVAL (INTERNAL MEDICINE – CARDIOMETABOLIC UNIT)
7. Private Practice Office attended around 15 patients daily. January, 2012 – February, 2015. Valencia –
 Venezuela.

PROFESSIONAL SOCIETIES

Associated member of Venezuelan Society of Internal Medicine (SVMI)
Member of American College of Physicians (ACP) # 01278950.

LECTURES

“PSYCHOLOGICAL FACTORS OF FIBROMYALGIA.” 3rd Venezuelan Expert Forum in Pain. Pfizer
Venezuela. May 2013

“DIAGNOSIS OF PATIENTS WITH HEART DISEASE.” Venezuelan Congress of Internal Medicine. May 2014.

MEDICAL SKILLS

1. CPR.
2. Electrocardiography.
3. Spirometry.
4. Phlebotomy technician.
5. Ambulatory Blood Pressure Monitoring.
6. Pain management.
7. Lumbar puncture (more than 150).
8. Enteral and Parenteral Nutrition – Metabolic support.
9. APPLICATIONS: Microsoft Office Suite, Chrome, Explorer, Social media management.
10. LANGUAGE: BILINGUAL - Spanish - Native. English – Fluently.

Vince Patel MDClinical Research Coordinator

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EDUCATION

1. Doctor of Medicine, Honors Graduate, Medical University of Lublin, Lublin, Poland, 2013-2019, Clinical GPA: 3.84 (82 weeks), Basic Science GPA: 3.12 (1.799 Hours)
2. Bachelor of Science in Biomedical Sciences, Minor: Public Health, Biophysics, University of South Florida, Tampa, FL, 2006-2010, GPA 3.00
3. High School Diploma, High Honors Graduate, Vocation Degree: Pre-Med/Health Science, Academy of Health Professions, Tampa Bay Technical Magnet High School, Tampa, FL, 2002-2006, GPA 4.00

WORK EXPERIENCE

1. Clinical Assistant –Psychiatry and Behavioral Neuroscience, University of South Florida, Morsani College of Medicine, 2021-2022
2. Clinical Assistant –Primary Care, CFP Physicians Group, Casselberry, FL, 2019-2020
3. Commercial Property Manager- Self Employed TVOX360 Holdings LLC, Tampa FL, 2016-2020
4. Director of Operations - First Desi Alliance LLC, India Cultural Center INC, Tampa, FL, 2008-2013
5. Certified Pharmacy Technician – Walgreens Pharmacy, Tampa, FL, 2005-2010

CLINICAL EXPERIENCE

1. Clinical Internship – Pathology, Family Medicine, ICU, Anesthesiology, Otolaryngology, Jackson Park Hospital, Chicago, IL, 2018-2019
2. Clinical Internship – Ophthalmology, Advocate Illinois Masonic Medical Center, Chicago, IL, 2019-2019
3. Clinical Internship – Internal Medicine, Geriatrics, Ob/Gyn, Pediatrics, Neurology, Radiology, Family Medicine, Adventist Health Systems, Chicago, IL, 2015-2016
4. Clinical Internship – Psychiatry, Brentwood Hospital, Shreveport, LA, 2015-2015
5. Clinical Internship – General Surgery, ER, Hem/Onc, Infectious Disease, Dermatology, Public Hospital 1 and 4, Lublin, Poland, 2014-2014

CO-CURRICULARS & RECOGNITIONS

1. President of Medical University of Lublin 4 Year American Student MD Curriculum
2. American Medical Association Member
3. American Academy of Family Physicians
4. USF Student Body President Runner Up
5. USF Chapter President of Delta Epsilon Psi National South Asian Service Fraternity, Inc
6. USF Student Government

CO-CURRICULARS & RECOGNITIONS

1. President of Medical University of Lublin 4 Year American Student MD Curriculum
2. American Medical Association Member
3. American Academy of Family Physicians
4. USF Student Body President Runner Up
5. USF Chapter President of Delta Epsilon Psi National South Asian Service Fraternity, Inc
6. USF Student Government

CERTIFICATIONS & CME

1. Good Clinical Practices Certification, TransCelerate Biopharma Inc, 2022
2. IATA Certification, Mayo Clinic, 2022
3. BLS & AED Program Certification, American Heart Association
4. Infection Control & OSHA Bloodborne Pathogen Standard Certification, NY State Department of Health
5. Bloodborne Pathogens Certification, American Academy of CPR & First Aid, Inc
6. HIPAA Awareness for Healthcare Providers Certification
7. ACLS Program Certification, American Heart Association
8. PALS Program Certification, American Heart Association

RESEARCH/CLINICAL TRIALS

1. TRAVERSE Study. M16-100: Testosterone Replacement Therapy for Assessment of long-term Vascular Events and Efficacy Response in Hypogonadal Men.
2. PROMINENT (K877-302): Pemafibrate to reduce cardiovascular outcomes by reducing triglycerides in patients with diabetes.
3. ANJ900D3501: A randomized, multicenter, double-blind, parallel-group, placebo-and comparator-controlled study to compare the glycemic effects, safety, and tolerability of metformin hydrochloride delayed-release tablets in patients with type 2 diabetes mellitus with varying renal function from normal up to CKD3B

4. D9488C00001: A Phase 3, International, Randomised, Double-blind, Placebo-controlled Study to Evaluate the Effect of Sodium Zirconium Cyclosilicate on Chronic Kidney Disease (CKD) Progression in Participants with CKD and Hyperkalaemia or at Risk of Hyperkalaemia
5. CSL346_2001: A Phase 2a, Double-blind, Randomized, Placebo-controlled, Proof of Concept Study of Vascular Endothelial Growth Factor (VEGF)-B Blockade with the Monoclonal Antibody CSL346 in Subjects with Diabetic Kidney Disease
6. I8F-MC-GPHL: Efficacy and Safety of Tirzepatide Once Weekly versus Placebo in Participants with Type 2 Diabetes Who Have Obesity or Are Overweight with Weight-Related Comorbidities (SURMOUNT-2)

Maria del Carmen Freire, PA-C.....Sub-Investigator

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EDUCATION

1. MPAS, Florida International University December 2017
2. GCP training certificate; CITI, December 2017
3. GCP training certificate Brookwood International Academy Dec 2019
4. BS-Cell and Molecular Biology, Minor in Dance Studies, University of South Florida 2015

WORK EXPERIENCE

1. Physician Assistant, West Orange Endocrinology, Ocoee, FL 2018-present
2. Office Assistant, Endocrine Associates of Florida, Ocoee FL, 2012-2013

SCHOOL ACTIVITIES/ LEADERSHIP

FIU Challenge Bowl Team, 2017

PRESENTATIONS/RESEARCH

1. Mandry, M. (2017). FIU MPAS Capstone: The Use of Inhaled Human Insulin in the Management of Type One Diabetes Mellitus.
2. Cox, R., Phillips, O., Fukumoto, J., Fukumoto, I., Parthasarathy, P. T., Mandry, M., Kolliputi, N. (2015). Resolvins Decrease Oxidative Stress Mediated Macrophage and Epithelial Cell Interaction through Decreased Cytokine Secretion. PLOS ONE PLoS ONE, 10(8)

PROFESIONAL SOCIETIES

1. Florida Academy of Physician Assistants
2. American Academy of Physician Assistants
3. American Society of Endocrine Physician Assistants
4. Member at Large, Pan American Medical Society, 2019-2021.

VOLUNTEER EXPERIENCE

Allergy and Immunology Research Assistant, 2014-2015

CONFERENCES

1. FAPA Winter Symposium 2017
2. FSDPA New Wave Dermatology Southeast Regional Conference 2017

Oscarina Herrera MD Sub-Investigator

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1510 Citrus Medical Court Ocoee, FL 34761 USA
Phone: (786) 3956330
Investigator@woendo.com



PROFESSIONAL EXPERIENCE

1. Clinical Trial Sub-Investigator May 2019 – Present West Orange Endocrinology, P.A.
2. Primary Care Physician CAC Florida Medical Center (HUMANA – CARE DELIVERY ORGANIZATION) Orlando, FL August 2013 - February 2018
3. Primary Care Physician CAC Florida Medical Center (CONVIVA Physician Group) Orlando, FL May 2018 - 2019
4. Medical Director Interamerican Medical Center Group LLC Orlando, FL 2019-present
5. Research Study Coordinator Department of Medicine Cardiovascular Division University of Miami / Jackson Memorial Hospital September 2008 – June 2010

EDUCATION

1. University of Zulia, School of Medicine. Maracaibo, Venezuela. Medical Doctor, MD Sep 1995 – Dec2002
2. English Language Institute, University of Florida (www.eli.ufl.edu) Gainesville, Fl. Aug 2005 Apr 2006
3. KAPLAN MED INSTITUTE (www.kaplanmedical.com). Miami, Fl. United States Medical Licensee Jul 2006 – Apr 2008
4. Internal Medicine Residency Lincoln Medical and Mental Health Center Affiliated to Weill Medical College of Cornell University New York, NY Jul 2010 – Jun 2013

INTERNSHIP

1. Hospital General del Sur “Dr. Pedro Iturbe” Edo. Zulia – Venezuela September 2003 – April 2005
2. Internship in Depts.: Pediatric, Adult Emergency, Outpatient clinic and Inpatient Service, Internal Medicine, Cardiology, Gastroenterology, Endocrinology, Epidemiology, Pulmonology and Surgery. In the same Internship Program: Rural Physician in charge the Outpatient 2003-2005
3. Outpatient-Inpatient Physician: Emergency Department, Hospital Villa del Rosario Edo. Zulia – Venezuela January 2003 – April 2003
4. Internal Medicine and Pediatric Hospital María Aracelis Alvarez Edo. Trujillo - Venezuela
5. May 2003 – August 2003
6. Internal Medicine Residency Lincoln Medical and Mental Health Center July 2010 – June 2013
Affiliated to Weill Medical College of Cornell University Bronx, NY

RESEARCH PROJECT/CLINICAL TRIALS

1. Gastroenterology

- A. Colorectal cancer in New York City (COLONY project). July 2010 – June 2013
- B. Evaluation of liver function for acutely elevated serum Aminotransaminase among patients seen & treated in an Inner City Community Hospital in New York. July 2010 – June 2013

2. Cardiology

- A. THE BALANCE Study: September 2008 – June 2010 Treatment of Hyponatremia Based on Lixivaptan in NYHA Class III/IV Cardiac Patient Evaluation. PI: Martin Bilsker MD/ Research coordinator: Oscarina Herrera MD.
- B. ROCKET Study: September 2008 – June 2010 Rivaroxaban Once-daily oral direct factor Xa inhibition Compared with vitamin K antagonism for prevention of stroke and Embolism Trial in Atrial Fibrillation. NEJM published on September 8 2011. PI from University of Miami: Martin Bilsker MD. Research Coordinator: Oscarina Herrera MD
- C. LOVAZA Capsules: September 2008 – June 2010 For prevention of recurrent episodes of Afib. PI: Martin Bilsker MD. Research Coordinator: Oscarina Herrera MD
- D. GENOMIC Project: September 2008 – January 2009 CAD and GENETIC. PI: David Seo MD. Research assistant: Oscarina Herrera MD University of Miami.

PRESENTATIONS/AWARDS

1. An elderly female patient presenting with spontaneous bilateral rectus sheath hematomas. Oscarina Herrera MD. December 2011. NYC, NY.
2. Cátedra de Pediatría (2001) Cátedra de Medicina Interna (2001) Cátedra de Farmacología (1999) Cátedra de Bioquímica (1997- 1998)
3. English as a Second Language.(ELS) Aug 2005 – Apr 2006
4. Reading and Writing Excellence, Grammar Publishing in Voices ELI Newsletter : Home-made remedies Apr 2006

CERTIFICATIONS AND LICENSE

1. Florida State Medical License Current
2. DEA Current



3. ABIM August 2013
4. ECFMG April 2008

TRAINING COURSES AND CONFERENCES

1. BLS July 2017
2. 6th Annual Contemporary Multidisciplinary Cardiovascular Conference November 2014
3. The Ohio State University Heart and Vascular Center Orlando, FL
4. Clinical Management of HIV in Adults in the era of Highly Active Antiretroviral Therapy
November 2014 Orlando, FL
5. Prevention of Medical Errors November 2014 Orlando, FL
6. ACLS/BLS October 2012
7. GCP Training Transcelerate Pharma Inc. February 2022

MEMBERSHIP AND ASSOCIATIONS

1. PAMA (Pan-American Medical Association) The Leading Physicians of the World
2. PAMA (Pan-American Medical Association) Treasurer, 2019-2021.
3. AMA (American Medical Association)
4. ACP (American College of Physician)
5. NEJM (New England Journal of Medicine)
6. VAMA (Venezuelan American Medical Association)