Silvia Inés Orio

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Education	• Medical Doctor, National University of Tucumán 1983 • Specialist in Endocrinology, University of Bs As 1989 • Higher Course in Diabetology, National University of Bs As 1991 • Thyroid Update Course Fundación Favaloro 2000 • Medical Researcher, Foundation for pharmacological and drug studies Prof. Luis M. Zieher 2005. • Good Clinical Practices FEFYM Foundation for Pharmacological and Drug Studies Prof. Luis M. Zieher ". 2007. • Good clinical practices Quintiles. 2012 • IATA Clinica Mayo standards, last update 2019 • Provision 6677/10 ANMAT, Novo Nordisk 2015 • Good Clinical Practice Brookwood International Academy, 2015 • Good clinical practices, Eli Lilly Jun 2017. • Data systems for research: Medidata, Inform, Rave, Oracle. • IATA Clinica Mayo standards, Oct 2021 • Good clinical practices, The Global Healt Network, Oct 2021. • Diploma in Good Practices in Biomedical Research. University of San Pablo.Tucumán. August 2020 to July 2021 (238 hours).

Current employment information	• **Investigaciones Médicas IMOBA SRL** Av Medrano 134 floor 6 CABA Physician coordinator and principal investigator in the area of endocrinology and diabetes from 2008 to the present. • **Consultorios Médicos Chacabuco. Merlo** Endocrinologist and diabetologist from January 2009 to the present • **CEM, San Justo** Endocrinologist and diabetologist from 2009 to the present.
License	**M.N 68.568** **M.P 37.906**
Clinical studies in the last 5 years	➢ 28431754DNE3001 CREDENCET Multicenter, randomized, double-blind, event-motivated, placebo-controlled study of the effects of canaglifozin on renal and cardiovascular outcomes in subjects with type II diabetes and diabetic nephropathy. Phase III. From 2015 to 2019. Principal investigator. Janssen. ➢ GSK716155 HARMONY: Long-term, randomized, double-blind, placebo-controlled study to determine the effect of biglutide in addition to standard blood glucose-lowering therapies on major cardiovascular events in patients with type 2 diabetes. From 2016 to 2018 Phase III. Glaxo. Principal Investigator. ➢ CLCZ696D2301: Multicenter, randomized, double-blind, parallel group study to evaluate the efficacy and safety of CLCZ696 compared with valsartan, on morbidity and mortality in patients with heart failure (NYHA class II-IV) with preserved ejection fraction. clinical trials, phase III, From 2016 to 2018, Novartis. Sub investigator. ➢ EFC13957: 6-month, multicenter, randomized, open-label, 2-arm, parallel-group study comparing the efficacy and safety of a new formulation of insulin glargine and Lantus injected once daily in children and adolescents aged 6 to 17 years of age with Type 1 Diabetes Mellitus with a 6-month safety extension period. From July 2016 to 2018. Phase III. Sanofi. Co-investigator. ➢ NN9068-4228 DUALTMVIII: Clinical study comparing long-term glycemic control of insulin degludec / liraglutide (IDegLira) versus insulin glargine therapy in subjects with 104-week duration of type 2 diabetes mellitus. From 2016 to 2018. Phase III.
Experiencia en	

Investigación clínica, (últimos 5 años)	Novo Nordisk. Principal Investigator. ➢ NN9924-4222 PIONEER 3: Long-term efficacy and safety of oral semaglutide versus sitagliptin in subjects with type 2 diabetes. Phase III. From 2016 to 2018. Principal investigator. Novo Nordisk. ➢ I8B-MC-ITRN Prospective, double-blind, randomized study of LY900014 compared with insulin Lispro in combination with insulin Glargine or insulin Degludec in adults with type 2 diabetes PRONTO-T2D. From 2016 to 2019. Phase III. Eli Lilly. Principal Investigator. ➢ I8B-MC-ITRM Prospective, double-blind, randomized study of LY900014 compared with Lispro insulin with an open-label treatment group with postprandial LY900014 in combination with insulin Glargine or insulin Degludec in adults with type 1 diabetes PRONTO-T1D. From 2016 to 2019. Phase III. Eli Lilly. Principal Investigator. ➢ CLCZ696D2301 Multicenter, randomized, double-blind, parallel-group, active-controlled study to evaluate the efficacy and safety of LCZ696, compared with valsartan, on morbidity and mortality in participants with heart failure (Class II-IV of NYHA) and preserved ejection fraction. From 2017 to the present. Phase 3. Novartis. Sub investigator. ➢ LIK066 Multicenter, randomized, double-blind, parallel-group, dose-finding study to evaluate the effect of 3 doses of LIK066 compared to placebo or pagliflozin in patients with type 2 diabetes mellitus with heart failure. From 2016 to 2018. Phase III. Novartis. Principal Investigator. ➢ EFC14828 –AMPLITUDE-O - Multicenter, randomized, double-blind, placebo-controlled, parallel group study to evaluate the effect of efpeglenatide on cardiovascular outcomes in patients with type 2 diabetes who are at high risk for cardiovascular disease. Sanofi Aventis. Phase III. From 2017 to Jun 2021. Principal Investigator. EFC14875- SCORED: Multicenter, randomized, double-blind, placebo-controlled study in parallel groups, to demonstrate the effects of zotagliphozin on cardiovascular and renal events in patients with type II diabetes, cardiovascular risk factors and moderate renal failure. Phase III. Sanofi Aventis. From 2017 to May 2021. Principal Investigator. cardiovascular risk and moderate renal failure. Phase III. Sanofi Aventis. Since 2017 March 2021. Principal investigator. ➢ ➢ Protocol H9X-MC-GBGL "A randomized, double-blind, parallel-arm study to study the efficacy and safety of investigational doses of Dulaglutide when added to Metformin in patients with type 2 diabetes mellitus." From 2018 to December

2019. Phase III. Principal Investigator. Eli Lilly.

- 1002-043 (CLEAR), entitled “Randomized, double-blind, placebo-controlled study to evaluate the effects of bempedoic acid (ETC-1002) on the occurrence of major cardiovascular events in patients with cardiovascular disease or at high risk of developing it, they do not tolerate statins ”. Phase III. Clixar. Coordinator of clinical studies. From 2018 to the present. Sub investigator.

- K-877-302 Prominent Pemafibrate to reduce cardiovascular outcomes by lowering triglycerides in patients with diabetes. From 2017 to the present. Phase III. Quintiles. Principal Investigator.

- OBS15151 Observational, cross-sectional and multinational study to describe glycemic control and quality of life in adult patients with type 1 diabetes. From 2018 to 2019. Sanofi Aventis. Principal Investigator.

- NN2211-4446: CAPTURE IO: Cross-sectional study, without intervention to capture the prevalence of cardiovascular diseases in patients with type 2 diabetes, an international observational study. From 2019 to 2020. Principal investigator. Novo Nordisk.

- DIREGL008168 DINAS AR: National, prospective, observational study to assess unmet needs in patients with type 2 diabetes treated with Basal Insulin. From 2018 to 2019. Sanofi Aventis. Principal Investigator.

- LPS15396 / ARTEMIS-DM: A multicenter, multinational, prospective, interventional, single-arm phase IV study evaluating the clinical efficacy and safety of 26 weeks of treatment with insulin glargine 300 U / ml (Gla-300) in patients with type 2 diabetes mellitus not controlled with basal insulin. From 2018 to the 2020. Sanofi Aventis. Principal Investigator.

- LPS15017: PREMIX, phase 3 study to compare lixi matching with insulin mix in patients with type 2 DBT. Sanofi Aventis. From January 2018 to 2020. Sanofi. Phase III. Principal Investigator.

- I8F-MC-GPGM Efficacy and safety of Ly3298176 once a week vs insulin glargine in patients with type 2 diabetes and high cardiovascular risk. From March 2018 to July 2021. Phase III. Eli Lilly. Principal Investigator.

	➢ I8F-MC-GPGH: Phase 3 open-label, randomized study comparing the effect of LY3298176 vs titrated insulin Degludec on the glycemic control of pts. with type 2 diabetes. Eli Lilly. From July 2018 to April 2021. Phase III. Eli Lilly. Principal Investigator. ➢ I8F-MC-GPGL: Randomized, open-label, phase 3 trial, comparing the efficiency and safety of Tirzepatide vs Semaglutide once a week as an add-on therapy to metformin in patients with type 2 DBT. Eli Lilly. From July 2019 to May 2021. Phase III. Eli Lilly. Principal Investigator. ➢ FINEART s-HF-(Bayer) Multicenter, randomized, double-blind, placebo-controlled parallel group study to evaluate the efficacy and safety of finerenone in morbidity and mortality in patients with Heart Failure (NYHA II-IV) and fraction left ventricular ejection >=40% (LVEF >=40%). Phase 3. Sub Investigator. From Oct 2020 to present. ➢ I8H-MC-BDCL A Phase 2 parallel, camparator- Controlled Trial to Evaluate the Safefty and Efficacy of LY3209590 in Insulin- Native with Type 2 Diabetes Mellitus. Eli Lilly. Principal Investigator From Nov 2020 to present. ➢ I8F-MC-GPHM Efficacy and SAfefty of Tirzepatide Once Weekly vs Placebo after an intensive Lifestyle Program participants without Type 2 Diabetes who have Obesiy or are Overweight with weight- related Comorbidities: Randomized Double Blind, Placebo Controlled Trial. Principal Investigator. From April 2021 to present. I8F-MC-GPHD Arandomized, phase 3, open label Trial comparing the effect of the addition of tirzepatide once weekly vs insulin lispro (U100)Three times daily in participants with type 2 diabetes inadequately controlled on insulin glargine (U100) with or without metformin. Principal Investigator. From Dec 2020 to present.

Signature: Date