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EXPERT SPOTLIGHT

Automated Glucose Clamp Procedures for Diabetes Clinical Research

Moises Hernandez, *Vice President, Clinical Research Unit (CRU)*

ProSciento's CRU is one of only three centers worldwide and the only center in the US that provides the automated glucose clamp methodology. ProSciento's automated glucose clamp technology, now in its second generation, is the result of having refined technical capabilities over nearly two decades of dedicated metabolic research.

During his tenure at ProSciento, Moises estimates that he has conducted or directly overseen more than 5,000 clamp procedures. His contributions in designing and conducting glucose clamp studies for metabolic drugs and devices have honed his expertise in clamp accuracy and quality parameters.

> *"ProSciento is a cohesive group of experts that work closely together and train cross-functionally so that our clients benefit from seamless, highly professional services for the conduct of their clinical studies."*

For our Expert Spotlight series, we had an opportunity to ask Moises questions about the challenges and benefits of glucose clamp studies.

Q: What pain points do you see in how CROs conduct clinical trials that utilize glucose clamping? How does ProSciento resolve these pain points?

A: The primary premise every researcher conducting clamps should look for is the quality of clamps, from a precision and accuracy point of view, and the second aspect is the reproducibility of clamps among the same participants, as well as the scalability to meet aggressive timelines. To accomplish this, a great degree of automatization and standardization is required. At ProSciento, we have the technology, leading expertise, and vast experience in conducting all glucose clamp variations.

Q: How has ProSciento and you specifically contributed to the advancement/progression of automated glucose clamp studies?

A: We have a clamp leadership team that meets regularly to study our clamp data and look for approaches to improve our technology and advance any necessary feature to support our automatization. Throughout the years, we've enhanced our automated intravenous glucose analysis and ensured its accuracy correlates to the gold standard glucose analysis. We've also extensively studied the variability of clamp quality among different populations, identifying key information to advise our researchers.

Q: What are some relevant metrics that would help an outsider understand the impact of ProSciento's automated glucose clamp technology and expertise on the conduct of clinical trials?

A: ProSciento conducts an average of 1,000 clamps a year for a diverse range of antidiabetic and metabolic drug and device candidates. ProSciento has also contributed to the evolution of varied clamp methodologies, from euglycemic to hypo and hyper glycemic clamps, as well as combining clamp methodologies with tracer studies. The specialized automated glucose clamp methodology utilizes a closed-loop system in which the variable of inter-operator proficiency is removed. The technology determines and infuses the required amount of exogenous glucose to maintain the target glucose level. A published algorithm calculates glucose requirements based on glucose measurements obtained minute-by-minute or at five-minute intervals. In this scenario, the operator is not required to make frequent judgments about the glucose infusion rate required to maintain the target glucose concentration and, thus, the potential for operator bias and inter-operator variability is largely eliminated. The integration of our glucose clamp technology and expertise, coupled with our high degree of scientific specialization in metabolic research, provides our clients a distinct advantage in achieving conclusive data results and meeting study timelines.

For further resources about ProSciento's automated glucose clamp studies, below are a sampling of scientific publications and posters.

Effect of Dawn Phenomenon on Glucose Infusion Rate During Glucose Clamp Studies In Subjects with Type 1 Diabetes. Franey B, Macias Pulido A, Morrow L Linda Morrow, Hompesch M. Poster presented at the Diabetes Technology Meeting, North Bethesda, Maryland. 2019 Nov.

Glucose Clamp Quality Parameters Among Study Populations. Macias Pulido A, Morrow L, Campos-Cortes G, Willard J, Hernandez M, Hompesch M. Poster presented at the Diabetes Technology Meeting, North Bethesda, Maryland. 2019 Nov.

Single-dose euglycaemic clamp studies demonstrating pharmacokinetic and pharmacodynamic similarity between MK-1293 insulin glargine and originator insulin glargine (Lantus) in subjects with type 1 diabetes and healthy subjects. Crutchlow M, Palcza J, Mostoller K, Mahon C, Barbour A, Marcos M, Xu Y, Watkins E, Morrow L, Hompesch M. Diabetes Obes Metab. 2018 Feb. DOI: 10.1111/dom.13084

Albiglutide does not impair the counter-regulatory hormone response to hypoglycaemia: a randomized, double-blind, placebo-controlled, stepped glucose clamp study in subjects with type 2 diabetes mellitus. Hompesch M, Jones-Leone A, Carr MC, Matthews J, Zhi H, Young M, Morrow L, Reinhardt RR. Diabetes Obes Metab. 2015 Jan; 17(1):82-90. doi: 10.1111/dom.12398.

Why ProSciento?

ProSciento is the leading provider of clinical research and patient engagement solutions for metabolic continuum diseases with unparalleled expertise in diabetes, obesity, and steatotic liver disease. As a full-service clinical research organization (CRO), ProSciento works with clients of all sizes worldwide to design and conduct multinational clinical trials, from early clinical development planning through phase III. With two decades as a leading scientific contributor to metabolic continuum research, ProSciento has trusted relationships with clients, partners, and patients, supporting the development of therapeutics and devices that make an important difference in the lives of individuals with metabolic diseases.

Schedule a conversation with one of our team members at BD@prosciento.com to learn how ProSciento can support your upcoming clinical trial.

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