



## Fractyl Health Announces Clinical Update on Revita Real World Registry in Germany and Launch of Revita+ Telehealth Program Combining Behavioral Recommendations with Revita Treatment for Type 2 Diabetes

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*Revita+ is a pioneering partnership between the West German Diabetes and Health Centre (WDGZ) and Fractyl Health, combining Revita with telehealth behavioral modification recommendations for patients with Type 2 Diabetes (T2D) in Germany*

*Case study from first patient in the Revita Real World Registry is now published and demonstrates clinical remission from Type 2 Diabetes three months post-treatment*

LEXINGTON, Mass.—([BUSINESS WIRE](#))— Fractyl Health, a metabolic therapeutics company pioneering new approaches to prevent and reverse type 2 diabetes (T2D), today announced clinical updates on the Revita Real World Registry in Germany and the launch of a new telehealth program, called Revita+. This innovative program, created in partnership with Professor Dr. Stephan Martin, Director of the WDGZ, a center of excellence for diabetes and metabolism, is designed to combine behavioral recommendations for patients with advanced metabolic diseases with the Revita treatment for patients with type 2 diabetes (T2D).

Revita+ is a scalable behavioral modification program created to reduce insulin and glucose excursions. The behavioral program aims to potentiate the impact of Revita, an endoscopic procedure that uses hydrothermal ablation to resurface the duodenal mucosa, a potential root cause of T2D. The goal is not only to tackle the root cause of T2D but also to establish behavioral habits that offer the potential to prevent the recurrence of disease.

The potential value of the Revita+ program for patients is underscored by the publication of a case study highlighting the interim clinical experience of the first patient enrolled in the Revita Real World Registry in Germany<sup>1</sup>. At three months post-procedure, HbA1c levels dropped from a baseline of 7.6% to 5.3% (normal glucose range is typically regarded as an HbA1c of 5.7% or less) while also enabling discontinuation of all three glucose-lowering agents the patient had previously been administered: metformin, a DPP4 inhibitor, and long-acting insulin. This patient also lost 6kg of weight (~ 20 pounds), triglyceride levels normalized from a baseline value of 363 mg/dL to 52 mg/dL, LDL cholesterol improved from 84 mg/dL to 65 mg/dL and elevated liver transaminase values improved significantly. The improvement in blood sugar control and other parameters of metabolic syndrome suggest a significant overall improvement in metabolic health.

“The initial clinical experiences with Revita DMR in Germany are promising and validate the outcomes observed in previous clinical studies,” said Professor Martin. “Revita+ shows the promise that a new treatment paradigm that focuses on addressing duodenal dysfunction in combination with nutritional modification aimed at preventing excessive insulin spikes may be beneficial for patients. We know that weight loss and metabolic improvements are achievable for people with T2D, but Revita+ represents a treatment approach that I believe may allow durable maintenance of metabolic benefit.”

To date, 15 patients treated since February 2023 at the first center in Germany have provided consent to participate in the Revita Registry. Periodic updates on the Revita Registry and real-world clinical outcomes for patients in Germany undergoing Revita treatment will be shared as the study continues to enroll in more sites.

### About Fractyl Health

Fractyl Health is focused on pioneering new approaches to the treatment of T2D. Despite advances in treatment over the last 50 years, T2D and obesity continue to be rapidly growing drivers of morbidity and mortality in the 21st century. Fractyl Health’s goal is to transform T2D treatment from chronic blood glucose management to disease-modifying therapies that target the organ-level root causes of the disease. Fractyl Health is a private organ-editing metabolic therapeutics company based in Lexington, MA. For more information, visit [www.fractyl.com](http://www.fractyl.com) or [www.twitter.com/FractylHealth](https://www.twitter.com/FractylHealth)

### About Revita®

Fractyl Health’s lead product candidate, Revita®, is based on the company’s insights surrounding the potential role of the gut in metabolic diseases. Revita is designed to remodel the duodenal lining via hydrothermal ablation (i.e., duodenal mucosal resurfacing) to edit abnormal intestinal nutrient sensing and signaling mechanisms that are a potential root cause of metabolic diseases. Revita has received a CE mark in Europe and, in January 2022, received reimbursement authorization through NUB in Germany. In the United States, Revita is for investigational use only under US law. A pivotal study of Revita in patients with inadequately controlled Type 2 Diabetes despite multiple medicines and insulin, called Revitalize 1, is currently enrolling in the

United States and Europe.

<sup>1</sup>Martin S and Beyna T, InFo Diabetologie 2023;17(3).

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