REMAIN-1

Midpoint Cohort Fact Sheet

First Randomized Data on Post-GLP-Weight Maintenance

GLP-1 medications are highly effective for weight loss, but most patients regain significant weight after stopping treatment. Typically this means 5–6% of total body weight (10–15 lbs) within 3 months[1]. Maintaining weight loss after discontinuing these drugs is one of the biggest unmet needs in obesity care today.

Revita® is the first investigational, non-drug procedure designed specifically to address this challenge. The REMAIN-1 Midpoint Cohort will deliver the first randomized, blinded data on Revita's potential to help patients keep weight off after GLP-1 discontinuation—critical evidence ahead of pivotal trial results in 2026.

[1]Based on typical rebound weight reported in clinical studies such as SURMOUNT-4 after discontinuation of GLP-1 therapy. Aronne et al. JAMA. 2024;331(1):38–48. doi:10.1001/jama.2023.24945; Wilding et al. Diabetes Obes Metab. 2022 Aug;24(8):1553-1564

FRACTYL health

About Revita

Revita is a procedure called duodenal mucosal resurfacing (DMR). It targets the duodenum, which is the first part of the small intestine located just beyond the stomach. The duodenum plays a key role in regulating hunger and body weight.

Over time, high-fat, high-sugar diets can damage the duodenal lining. This damage may impair its ability to send accurate appetite and satiety signals to the brain. The resulting disruption in signaling is thought to drive weight regain and contribute to obesity and type 2 diabetes.

Revita uses targeted heat to remove the damaged duodenal lining. This allows the lining to regrow and may restore healthy gut-brain communication, helping patients maintain weight loss after stopping GLP-1 drugs.

About the REMAIN-1 Study

REMAIN-1 is a randomized, double-blind clinical study evaluating Revita compared to a sham (placebo-like) procedure in adults with obesity who:

- Have lost at least 15% of their body weight on the GLP-1 drug tirzepatide
- Wish to discontinue therapy without regaining weight

The study's goal is to determine whether Revita can maintain weight loss by restoring healthy appetite-regulating signals between the gut and brain.

The Three Cohorts in REMAIN-1

The pivotal REMAIN-1 study includes three distinct patient cohorts:

1. REVEAL-1 Cohort

An open-label group of people with obesity who have lost at least 15% of their weight on a GLP-1 drug and then discontinued therapy before receiving Revita. Designed to provide early, real-world insights into how Revita performs after GLP-1 discontinuation.

2. Midpoint Cohort

A smaller, randomized, double-blind group that will deliver the first controlled data on Revita's ability to maintain weight loss after stopping GLP-1s.

3. Pivotal Cohort

A large, randomized, double-blind cohort of 315 participants evaluating the primary and secondary endpoints needed for regulatory submission.

This staged approach allows Revita to be evaluated first in an open-label setting, then in an early randomized group, and finally in the full pivotal trial to confirm safety and efficacy.

About REMAIN-1 Midpoint Cohort

The **Midpoint Cohort** is an early, randomized, double-blind cohort within REMAIN-1, enrolling 45 participants.

People in the study:

- Start tirzepatide at enrollment and lose at least 15% of their body weight
- Discontinue tirzepatide
- Are randomized 2:1 to receive either Revita or a sham procedure

Why it is important:

This cohort is the first randomized, blinded test of Revita's effect on post–GLP-1 weight maintenance. It will provide an important early signal of efficacy ahead of the larger 315-patient pivotal cohort, which will deliver primary endpoint data in H2 2026.

REMAIN-1 Midpoint Cohort Timeline

3-month (12-week) data:

Expected September 2025

6-month (24-week) data:

Expected Q1 2026

**Disclaimer: Information on the products of the diseases contained herein is not intended to provide medical advice and/or treatment guidance.*
**Revita is for investigational use only in the United States. Revita has a CE mark in the EU/UK.*