Topline results from REVITA-2: The first randomized, double-blind, sham-controlled, prospective, multicenter study of duodenal mucosal resurfacing (DMR) efficacy, safety, and impact on NASH biomarkers in T2D

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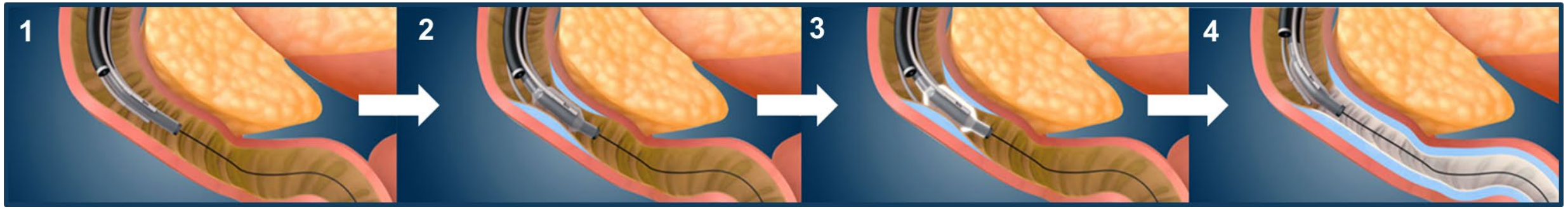
Introduction

- Novel, disease-modifying approaches are needed to treat insulin resistance–related metabolic diseases (eg, NAFLD/NASH and T2D)
- The **duodenum** is a key metabolic signaling center and critical regulator of metabolic homeostasis[1]
  - High-fat and sugar diets cause hyperplasia of duodenal lining, altering hormonal signaling and nutrient absorption from the duodenum, which can lead to abdominal obesity, insulin resistance, impaired glucose metabolism, hyperinsulinemia, dyslipidemia, and high blood pressure[2]
  - Duodenal bypass surgery (eg, RYGB) reverses metabolic disease[3]: NAFLD/NASH[4], T2D[5,6], PCOS[7,8], often co-existing in the same patient
- Targeting duodenal mucosal hyperplasia is a potential therapeutic option for treating insulin resistance–related metabolic diseases[1]

1. Van Baar et al., *Gastroenterology*. 2018;154:773. 2. Cherrington et al., *Gastrointest Endosc Clin N Am*. 2017;27:299-311. 3. Cummings et al., SOARD. 2007;3:109-115. 4. Lassailly et al., *Gastroenterology*. 2015;149:379. 5. Mingrone et al., *NEJM*. 2012;366:1577. 6. Schauer et al., *NEJM*. 2012;366:1567. 7. Jamal et al., *Surg Obes Relat Dis*. 2012;8:440–4. 8. Skubleny et al., *Obes Surg*. 2016;26:169. RYGB = roux-en-Y gastric bypass; NAFLD = nonalcoholic fatty liver disease; NASH = nonalcoholic steatohepatitis; PCOS = polycystic ovary syndrome; T2D = type 2 diabetes.

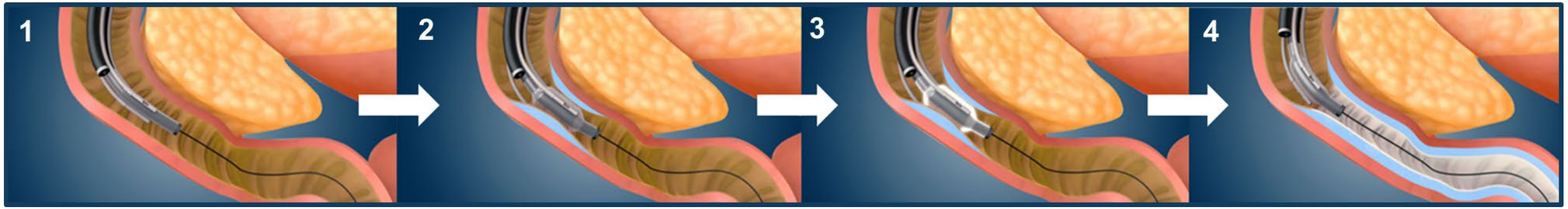
DMR: A novel, minimally invasive, outpatient, upper endoscopic procedure



- Revita® DMR catheter is designed to perform submucosal lift and hydrothermal ablation of hyperplastic duodenal mucosa, promote healthy epithelial regrowth within 12 weeks, and reduce insulin resistance and hyperinsulinemia[1,2]

1. Hadefi A et al., *Dig Dis*. 2018;36:322-324. 2. Rajagopalan H et al., *Diabetes Care*. 2016. 3. Cherrington A et al., *Gastrointest Endoscopy Clin N Am*. 2017;27:299-311. 4. Van Baar A et al., *Gut*. 2019; pii: gutjnl-2019-318349.
5. Haidry R et al., *GIE*. 2019; 673 - 681.e2. 6. van Baar ACG et al., DTM 2019 poster VAN 19122D. REVITA-2 NCT02879383
DMR = duodenal mucosal resurfacing; NAFLD = nonalcoholic fatty liver disease; NASH = nonalcoholic steatohepatitis; T2D = type 2 diabetes.

DMR: A novel, minimally invasive, outpatient, upper endoscopic procedure



- DMR is a well-tolerated procedure with few, self-limited side effects[3-5]

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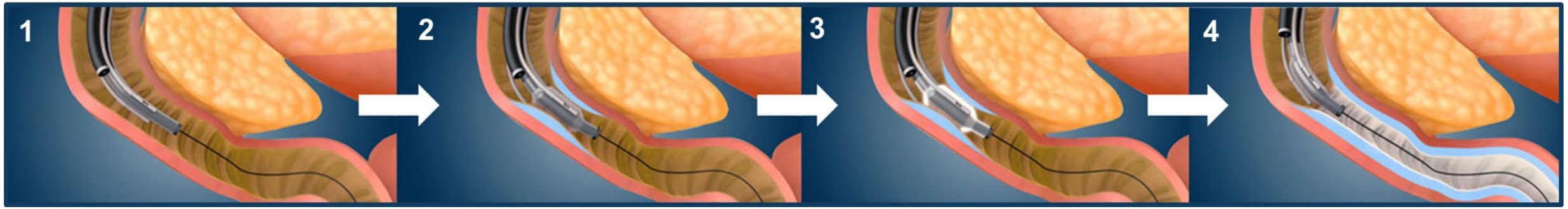

- DMR is a well-tolerated procedure with few, self-limited side effects[3-5]
- Prior studies (eg, REVITA-1) showed a single DMR procedure durably improves hepatic and glycemic parameters through 2 years in patients with T2D, indicating potential benefit in T2D with concomitant NAFLD/NASH[3-6]

1. Hadefi A et al., *Dig Dis*. 2018;36:322-324. 2. Rajagopalan H et al., *Diabetes Care*. 2016. 3. Cherrington A et al., *Gastrointest Endoscopy Clin N Am*. 2017;27:299-311. 4. Van Baar A et al., *Gut*. 2019; pii: gutjnl-2019-318349.
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DMR = duodenal mucosal resurfacing; NAFLD = nonalcoholic fatty liver disease; NASH = nonalcoholic steatohepatitis; T2D = type 2 diabetes.

REVITA-2: Prospective, sham-controlled study of the effect of DMR on hepatic and glycemic parameters in patients with sub-optimally controlled T2D across 11 sites (9 in EU, 2 in Brazil)

Objective

Demonstrate DMR efficacy and safety compared with sham for the treatment of suboptimally controlled T2D

Key Inclusion Criteria

- Aged 28 – 75 years
- T2D with evidence of preserved insulin secretion (fasting insulin > 7.0 µU/ mL)
- HbA1c 7.5 – 10%
- BMI ≥ 24 and ≤ 40 kg/m2
- On ≥ 1 oral antidiabetic medication (≥ 1 must be metformin)
- No medication or dose changes 12 weeks prior to study entry
- Able to comply with study and understand/sign informed consent

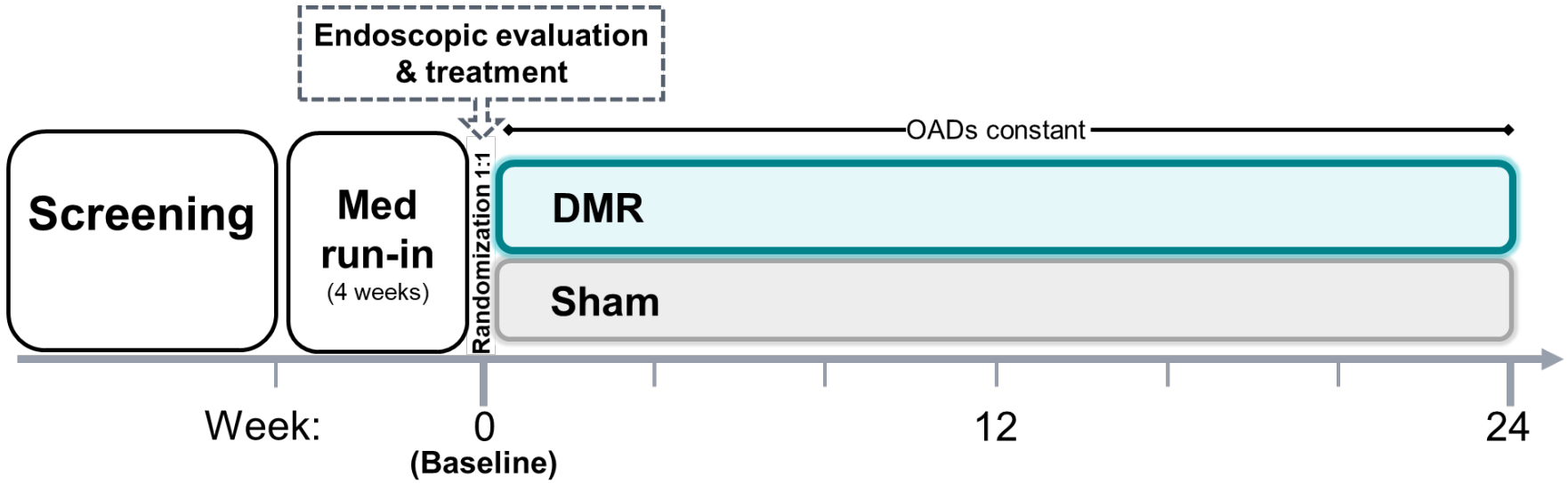
Key Exclusion Criteria

- Current use of insulin or GLP-1
- History of severe hypoglycemia
- Known autoimmune disease
- Active *H. pylori* infection
- Previous GI surgery (including bariatric)
- Participating in another ongoing clinical trial of an investigational drug or device

Data on File, Fractyl Laboratories Inc.

BMI = body mass index; GI = gastrointestinal; GLP-1 = glucagon-like peptide-1; HbA1c = hemoglobin A1c; T2D = type 2 diabetes.

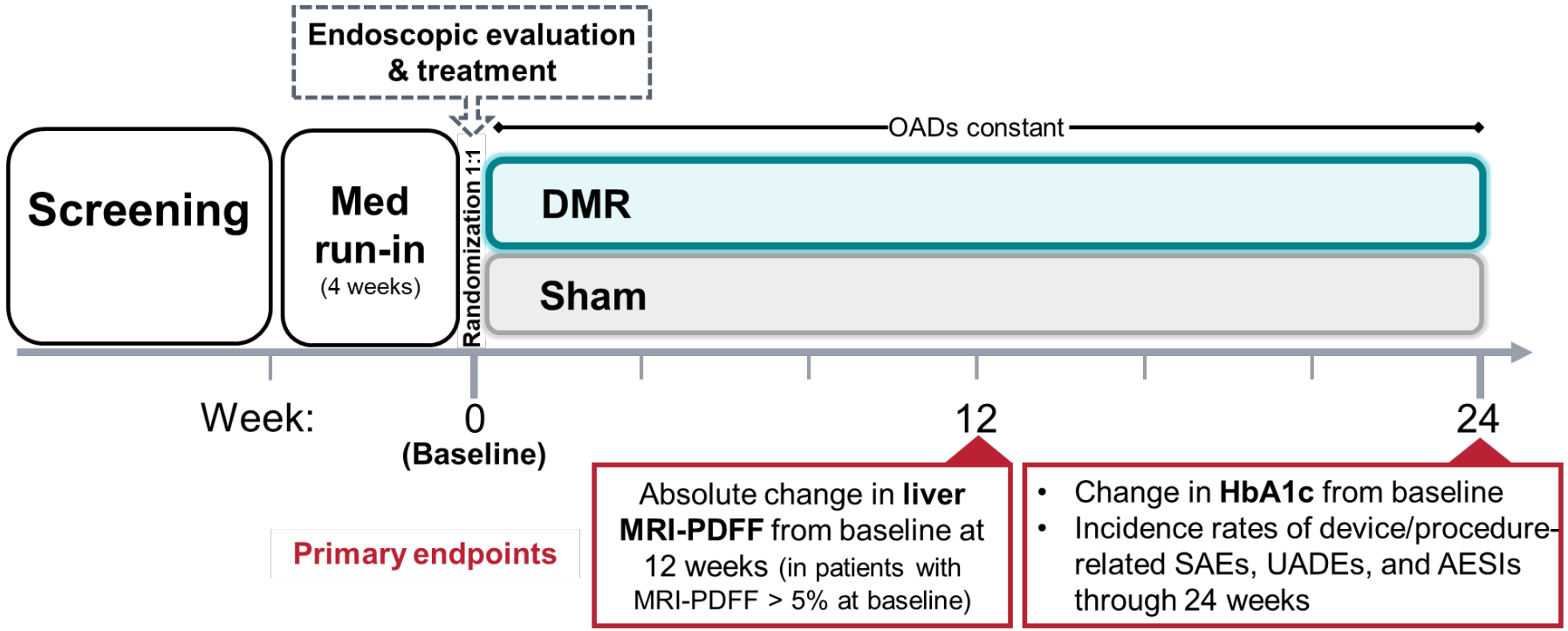
REVITA-2: Study design



Data on File, Fractyl Laboratories Inc.

AESI = adverse event of special interest; ALT = alanine aminotransferase; AST = aspartate aminotransferase; BG = blood glucose; BMI = body mass index; DMR = duodenal mucosal resurfacing; MRI-PDFF = magnetic resonance imaging proton density fat fraction; NAFLD = nonalcoholic fatty liver disease; NASH = nonalcoholic steatohepatitis; OAD = oral antidiabetic medication; SAE = serious adverse event; T2D = type 2 diabetes; UADE = unanticipated adverse device effects.

REVITA-2: Study design



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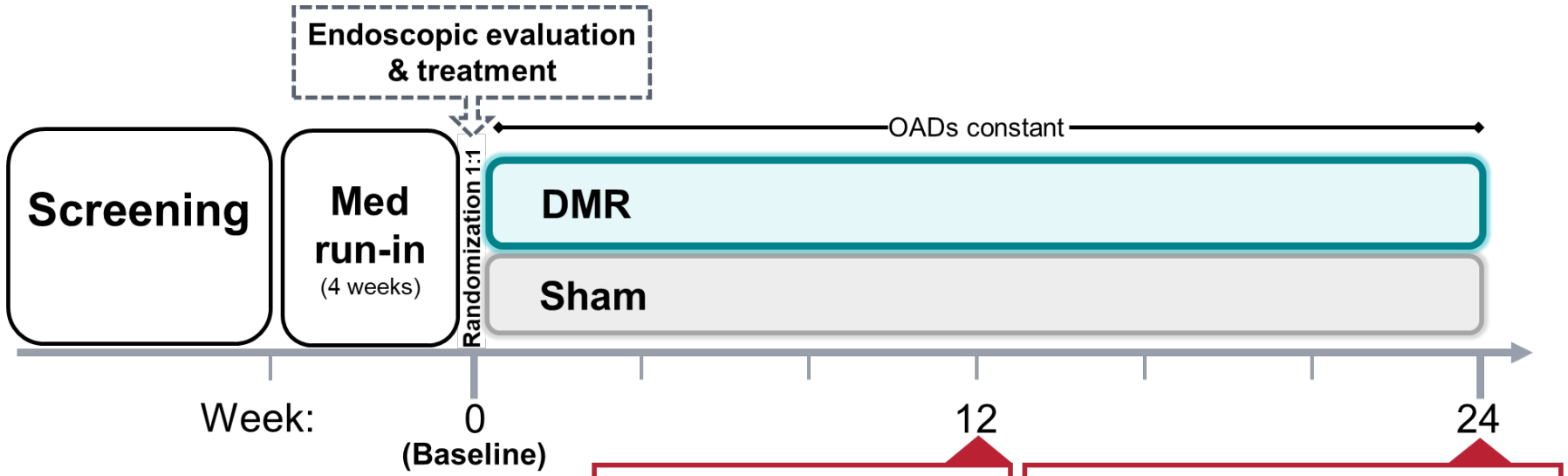
REVITA-2: Study design



Primary endpoints

- Absolute change in **liver MRI-PDFF** from baseline at 12 weeks (in patients with MRI-PDFF > 5% at baseline)
- Change in **HbA1c** from baseline
- Incidence rates of device/procedure-related SAEs, UADEs, and AESIs through 24 weeks

Selected secondary endpoint

- Relative change from baseline in liver MRI-PDFF in patients with MRI-PDFF > 5% at baseline

Data on File, Fractyl Laboratories Inc.

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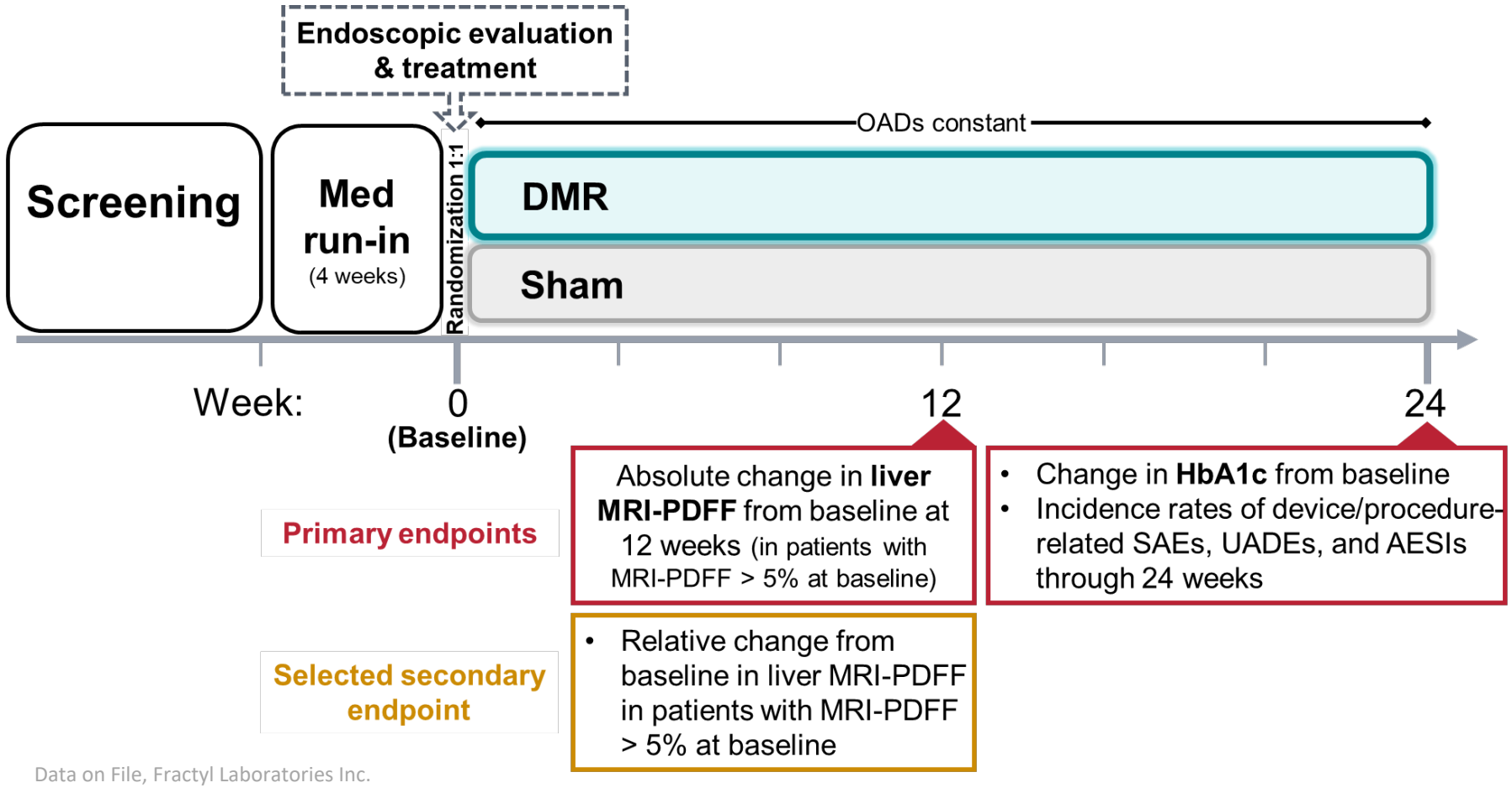
REVITA-2: Study design



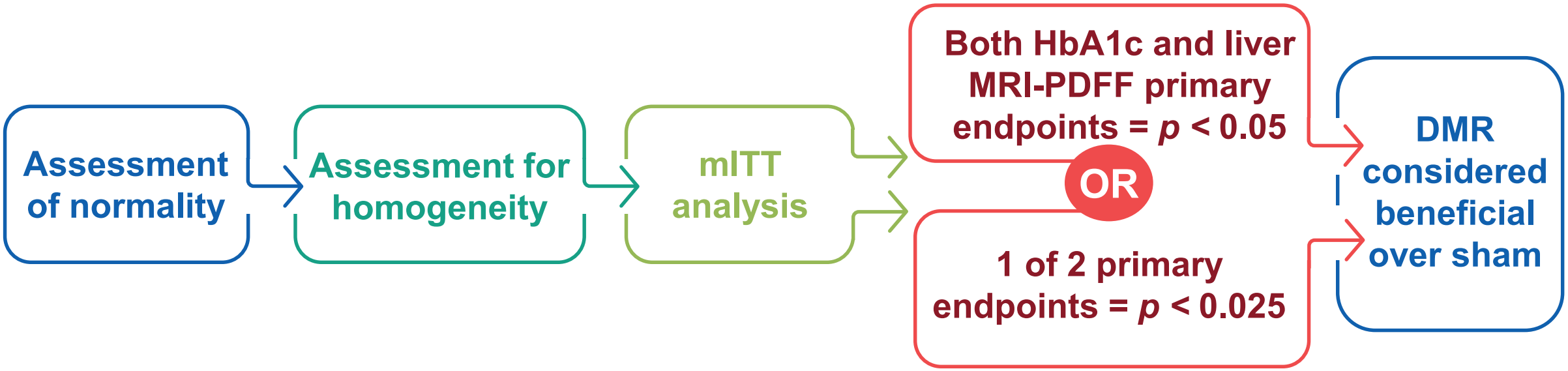
Analysis populations

- **Modified intent-to-treat (mITT):** All randomized patients in whom the procedure was attempted and who have a baseline measurement for ≥ 1 primary endpoint (primary analysis population)
- **Per-protocol (PP)**: Subset of mITT patients who received the treatment to which they were randomized, excluding patients with major protocol deviations

Data on File, Fractyl Laboratories Inc.

AESI = adverse event of special interest; ALT = alanine aminotransferase; AST = aspartate aminotransferase; BG = blood glucose; BMI = body mass index; DMR = duodenal mucosal resurfacing; MRI-PDFF = magnetic resonance imaging proton density fat fraction; NAFLD = nonalcoholic fatty liver disease; NASH = nonalcoholic steatohepatitis; OAD = oral antidiabetic medication; SAE = serious adverse event; T2D = type 2 diabetes; UADE = unanticipated adverse device effects.

REVITA-2 statistical methods: How success was defined in SAP



Prespecified interaction statistical test **assessed homogeneity** across geographic regions

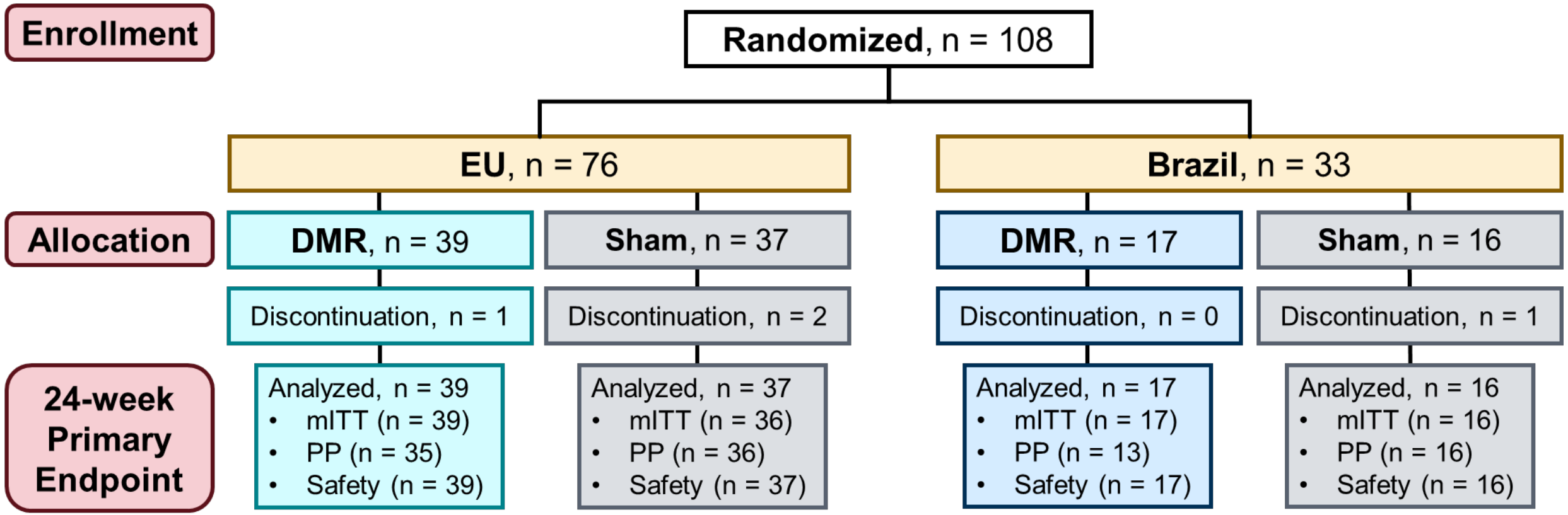
Brazil not homogeneous to European countries in hepatic and glycemic endpoints, regardless of treatment group

Brazilian and European populations not poolable, analyses were stratified, and **mITT results separated by region**

Data on File, Fractyl Laboratories Inc.

DMR = duodenal mucosal resurfacing; mITT = modified intent to treat; MRI-PDFF = magnetic resonance imaging proton density fat fraction; SAP = statistical analysis plan.

REVITA-2: Patient disposition



Data on File, Fractyl Laboratories Inc.
DMR = duodenal mucosal resurfacing; EU = European Union; mITT = modified intent to treat; PP = per-protocol.

REVITA-2: Patient demographics and baseline characteristics (mITT)

Characteristic	EU			Brazil		
	DMR (N = 39)	Sham (N = 36)	*p* value	DMR (N = 17)	Sham (N = 16)	*p* value
Age, years	59.0 (40.0, 72.0)	56.5 (35.0, 75.0)	0.62	56.0 (35.0, 72.0)	59.5 (42.0, 73.0)	0.15
Male, n (%)	30 (76.9)	28 (77.8)	0.93	9 (52.9)	8 (50.0)	0.87
Race, n (%)			0.60			0.69
White	25 (64.1)	21 (58.3)		12 (70.6)	13 (81.3)	
Other	1 (2.6)	3 (8.3)		5 (29.4)	3 (18.8)	
Undisclosed	13 (33.3)	12 (33.3)		0	0	
Weight, kg	93.1 (64.8, 155.0)	94.5 (66.6, 113.4)	0.66	89.0 (61.1, 109.6)	87.8 (71.9, 112.0)	0.63
BMI, kg/m^2	31.4 (23.6, 39.5)	30.4 (24.2, 39.6)	0.16	32.3 (25.5, 37.4)	31.6 (26.1, 37.9)	0.93
Liver MRI-PDFF, %	16.5 (5.5, 33.0)	16.1 (5.6, 33.8)	0.50	16.5 (7.0, 31.8)	17.0 (7.0, 33.9)	0.74
> 5% at baseline, n (%)	33 (85)	27 (75)	0.25	15 (88.2)	15 (93.8)	0.99
ALT, U/L	31.0 (11.0, 76.0)	29.0 (12.0, 162.0)	0.65	25.0 (12.0, 53.0)	26.5 (13.0, 49.0)	0.40
AST, U/L	21.0 (11.0, 44.0)	19.5 (10.0, 131.0)	0.31	20.0 (12.0, 58.0)	19.0 (12.0, 33.0)	0.47
Fasting glucose, mg/dL	191.0 (122.0, 313.0)	185.5 (110.0, 344.0)	0.68	190.0 (141.0, 289.0)	182.0 (119.0, 263.0)	0.23
HbA1c, %	8.1 (7.5, 10.0)	8.2 (7.5, 10.0)	0.45	8.6 (7.5, 9.6)	8.2 (7.5, 9.4)	0.21
C-peptide, ng/mL	2.5 (0.7, 4.9)	2.3 (1.5, 5.0)	0.48	3.2 (1.6, 7.6)	2.5 (1.7, 5.9)	0.36
Fasting insulin, mU/L	9.8 (2.4, 22.6)	8.4 (3.9, 17.6)	0.08	14.2 (4.8, 34.3)	12.0 (5.2, 23.2)	0.40

mITT population data for continuous variables are presented as median (min, max), unless otherwise noted.

**p* values are from Mann-Whitney U test for continuous variables due to non-normality and chi-squared test (or Fisher's exact test when appropriate) for categorical variables, unless otherwise specified. If the baseline value was missing for a given variable and patients, the screening value was used in its place prior to calculating the descriptive statistics. All *p* values are two-sided.

[a]mITT population defined as all randomized subjects in whom the study procedure (DMR or sham) is attempted and who have a baseline measurement for at least one primary endpoint.

ALT = alanine aminotransferase; AST = aspartate aminotransferase; BMI = body mass index; DMR = duodenal mucosal resurfacing; HbA1c = hemoglobin A1c; MRI-PDFF = magnetic resonance imaging proton density fat fraction.

Data on File, Fractyl Laboratories Inc.

REVITA-2: Favorable safety profile through 24 wks post-DMR

	EU		Brazil	
	DMR (N = 39)	Sham (N = 36)	DMR (N = 17)	Sham (N = 16)
Summary of device-/procedure-related				
SAE, n (%)	0	0	2 (11.8)	0
UADE, n (%)	0	0	0	0
AESI, n (%)	13 (33.3)	10 (27.0)	12 (70.6)	10 (62.5)
Most common (≥ 5%) device-/procedure-related AESI				
Gastrointestinal disorders	11 (28.2)	8 (21.6)	8 (47.1)	3 (18.8)
Abdominal pain	6 (15.4)	2 (5.4)	4 (23.5)	0
Abdominal pain upper	3 (7.7)	2 (5.4)	2 (11.8)	2 (12.5)
Diarrhea	1 (2.6)	3 (8.1)	1 (5.9)	1 (6.3)
Nausea	1 (2.6)	0	2 (11.8)	0
Vomiting	2 (5.1)	0	1 (5.9)	0
Metabolism and nutrition disorders	3 (7.7)	3 (8.1)	8 (47.1)	9 (56.3)
Hypoglycemia	3 (7.7)	3 (8.1)	8 (47.1)	9 (56.3)

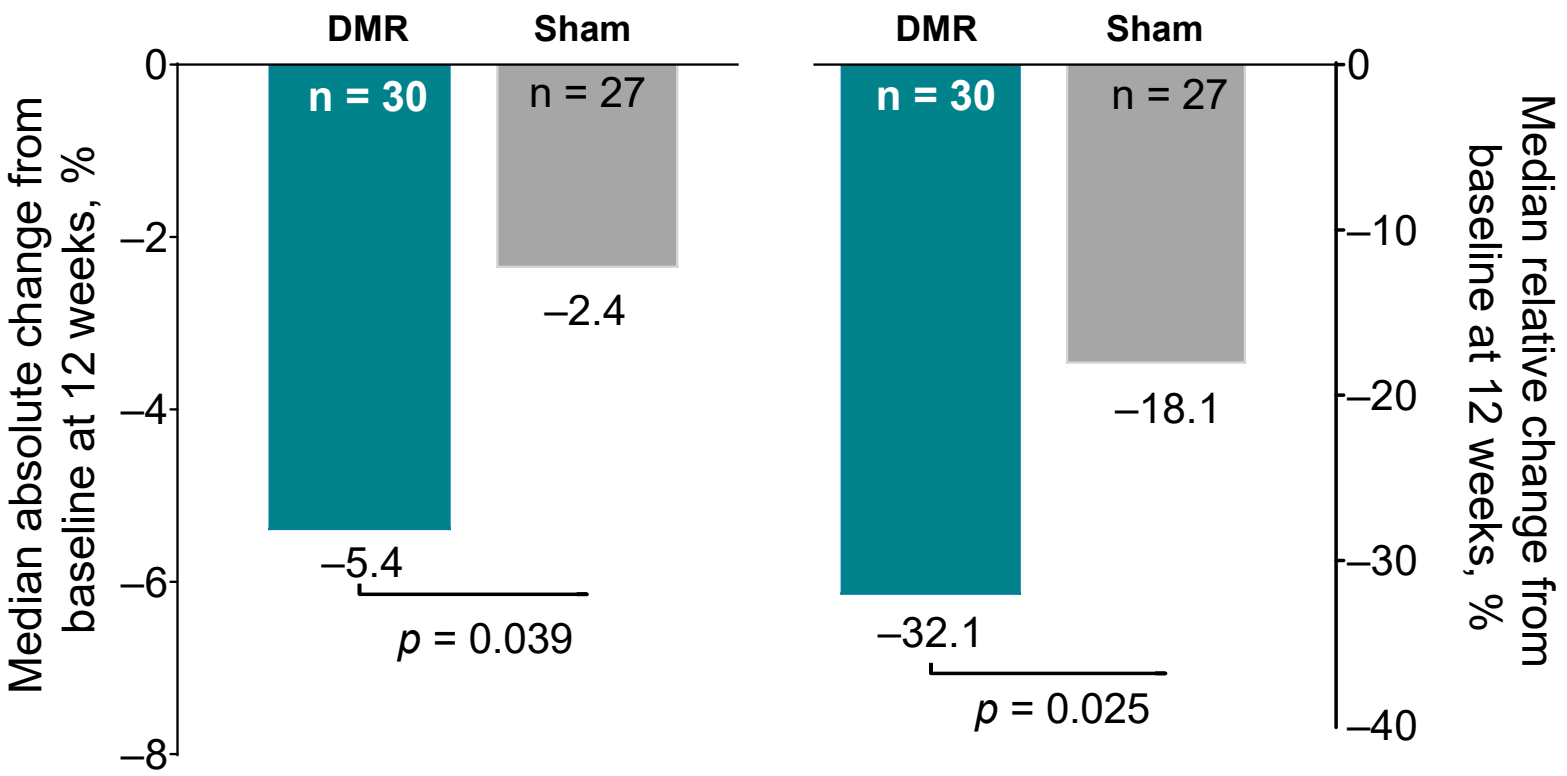
Data are presented as n (%), with n as the number of patients with an event. AESI = adverse event of special interest; DMR = duodenal mucosal resurfacing; SAE = serious adverse event; UADE = unanticipated adverse device effects.

Data on File, Fractyl Laboratories Inc.

REVITA-2: DMR significantly improves liver fat content

Changes in Liver MRI-PDFF in Patients with > 5% Liver Fat Content at Baseline (mITT)

Baseline median (min, max) liver MRI-PDFF: 16.1 (5.5, 35.8)



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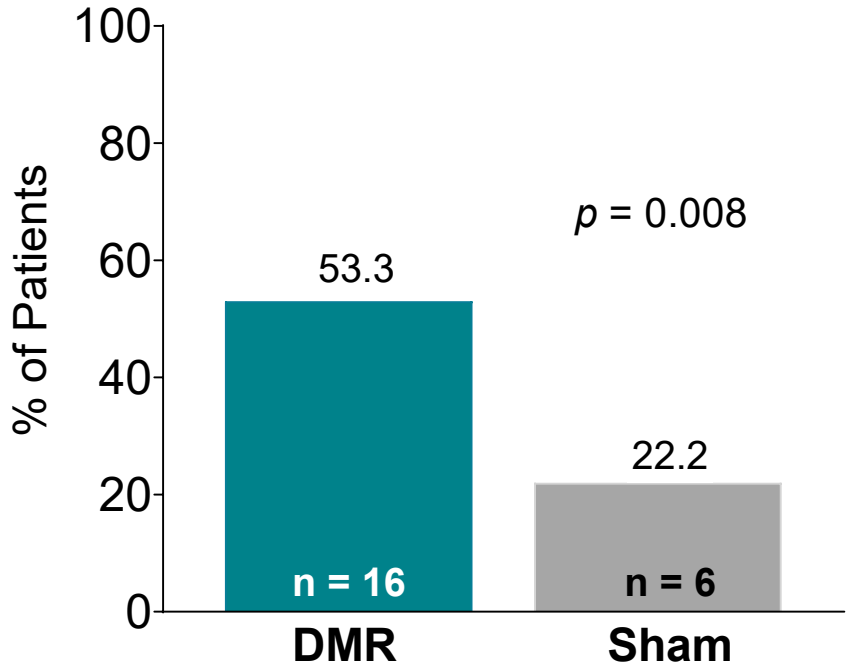
Treatment comparison one-sided *p* value based on ANCOVA model with Multiple Imputation on the rank values (modified ridit scores). Via multiple imputation, analysis is based on all patients in the population of interest where post-rescue values are first set to missing. ANCOVA = analysis of covariance; DMR = duodenal mucosal resurfacing; MRI-PDFF = magnetic resonance imaging proton density fat fraction.

REVITA-2: Exploratory hepatic analyses

Responder Analysis: > 30% reduction in relative liver MRI-PDFF from baseline to week12 (mITT)



Change in hepatic transaminases from baseline at 12 weeks

Parameter	DMR N = 39	Sham N = 36	*p* value
ALT, U/L	n = 36	n = 36	
Median (min, max)	–4.5 (–37.0, 13.0)	–2.0 (–36.0, 43.0)	0.143
AST, U/L	n = 32	n = 31	
Median (min, max)	–1.5 (–18.0, 9.0)	–1.0 (–37.0, 12.0)	0.117

Data are presented as median (min, max). One-sided *p* value based on ANCOVA model on the rank values (modified ridit scores) in mITT population for change from baseline to 12 weeks DMR vs. sham. ALT = alanine aminotransferase; AST = aspartate aminotransferase; DMR = duodenal mucosal resurfacing.

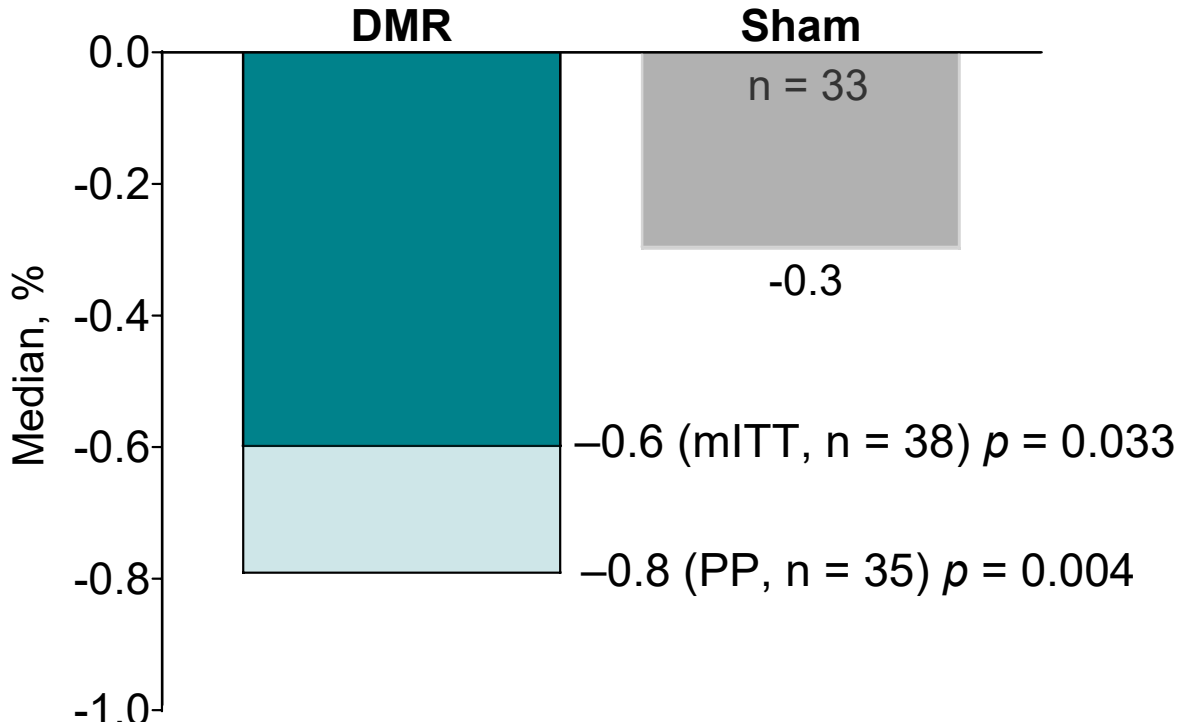
Large magnitude and clinically meaningful reductions in liver fat content

Data on File, Fractyl Laboratories Inc.
MRI-PDFF treatment comparison (DMR vs. SHAM) one-sided *p* value from chi-square test with no imputation of missing data and values post-rescue medication are set to missing. DMR = duodenal mucosal resurfacing; MRI-PDFF = magnetic resonance imaging proton density fat fraction.

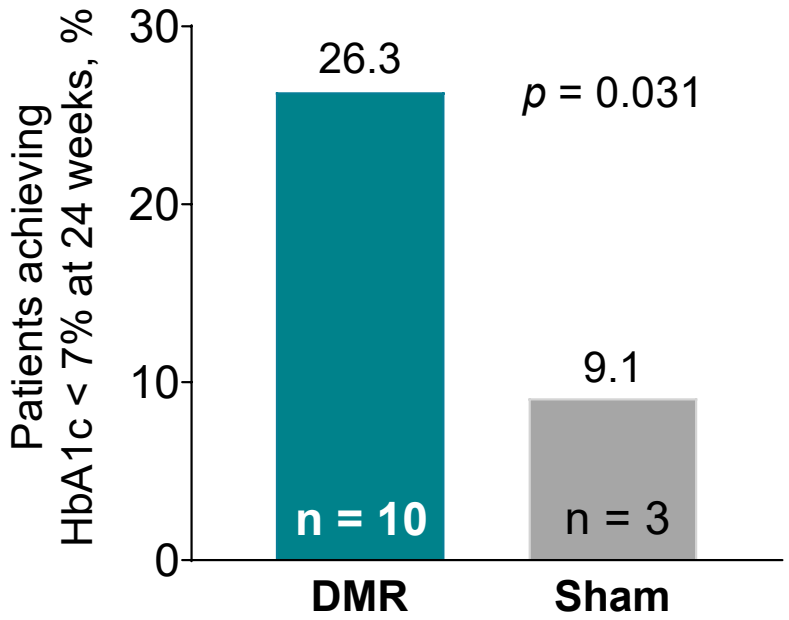
REVITA-2: DMR positively impacts glucose metabolism

Change in HbA1c from baseline to 24 weeks

Baseline median (min, max) HbA1c: 8.1 (7.5, 10.0)



Responders Analysis: HbA1c (mITT)



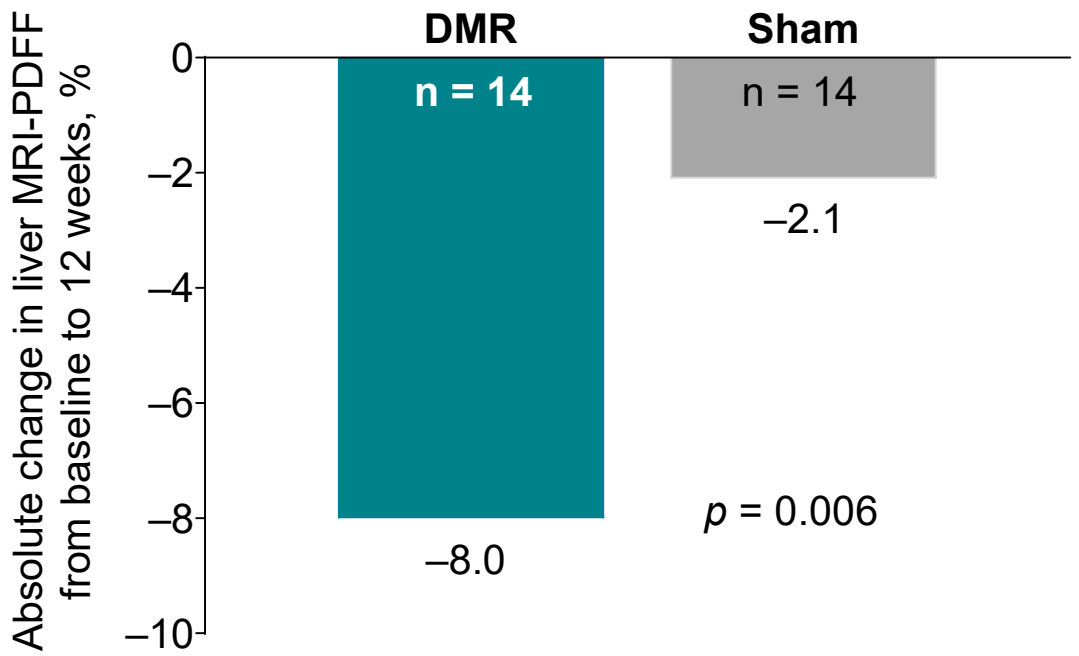
Data on File, Fractyl Laboratories Inc.

Left panel: Treatment comparison one-sided *p* value based on ANCOVA model with Multiple Imputation on the rank values (modified ridit scores). Via multiple imputation, analysis is based on all patients in the population of interest. Right panel: Treatment comparison (DMR vs. SHAM) one-sided *p* value from chi-square test with no imputation of missing data and values post-rescue medication are set to missing.

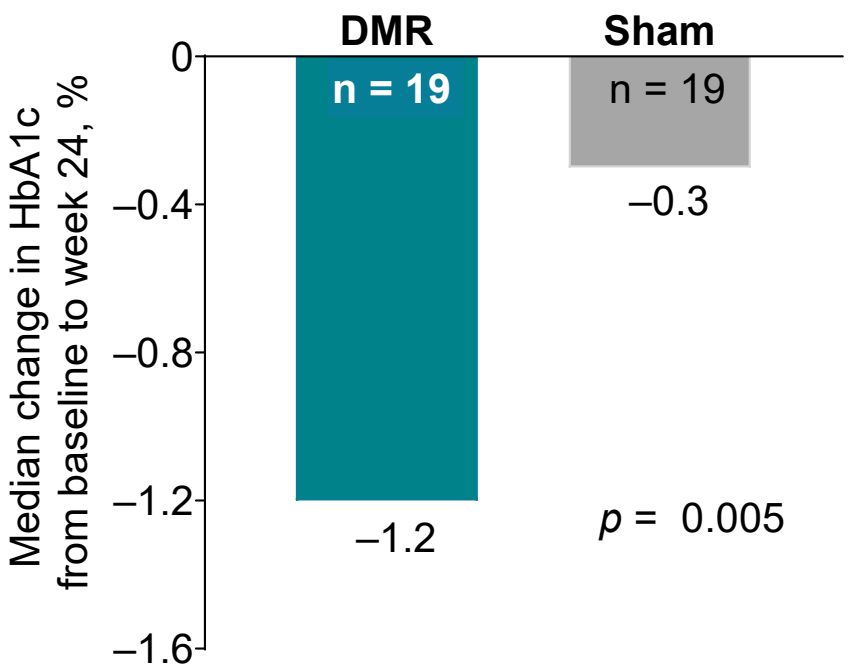
2 people missing Hba1c at week 24; 1 person set to missing post-rescue medication = 72 people in sample of 75 Europeans (PP). Four patients in mITT excluded from PP population. DMR = duodenal mucosal resurfacing; FPG = fasting plasma glucose; HbA1c = hemoglobin A1c; PP = per-protocol.

REVITA-2: Significantly greater reductions in liver MRI-PDFF and HbA1c in patients with baseline FPG ≥ 180 mg/dL

Baseline median (min, max) liver MRI-PDFF: 20.3 (8.0, 35.8)[1]



Baseline median (min, max) HbA1c: 8.5 (7.7, 10.0)[1]



Greater benefit in patients (PP) with higher FPG at baseline[2] supports the role of hepatic IR in NAFLD/NASH and T2D

1. Data on File, Fractyl Laboratories Inc. 2. Rajagopalan H, et al., *Diabetes Care*. 2016;39:2254. Treatment comparison (DMR vs. SHAM) one-sided *p* value from ANCOVA on ranks (modified ridit scores) model with no imputation of missing data and values post-rescue medication are set to missing with baseline value and the change from screening to baseline value as covariates in the model. Analyses presented were in complete casers.

DMR = duodenal mucosal resurfacing; FPG = fasting plasma glucose; MRI-PDFF = magnetic resonance imaging proton density fat fraction; T2D = type 2 diabetes; PP = per-protocol.

REVITA-2: Conclusions

- DMR is a novel intestinal-targeted therapy for T2D ± NAFLD with sustained response up to 6 months in this placebo-controlled study
  - REVITA-1 study demonstrated durable glycemic and hepatic improvements through 2 years[1]
- Results from REVITA-2 validate that the duodenum is a therapeutic target and raise important mechanistic questions
- DMR is an important new option for patients with T2D ± NAFLD/NASH with focus on disease reversal rather than management, particularly considering polypharmacy burden in these patients
- DMR has a safety and tolerability profile encouraging for broad therapeutic applicability in these disease states

1. van Baar ACG et al., DTM 2019 poster VAN 19122D. DMR = duodenal mucosal resurfacing; NAFLD = nonalcoholic fatty liver disease; NASH = nonalcoholic steatohepatitis; T2D = type 2 diabetes.