FRACTYL® health

What's Next in Metabolic Disease Treatment?

ADA Investor Day| June 24, 2024

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Welcome and Introduction to Fractyl Health

Harith Rajagopalan, MD, PhD

Co-Founder and Chief Executive Officer, Fractyl

Our purpose

To defend humanity from metabolic disease

Our mission

To develop transformative therapies that can prevent and hopefully cure metabolic disease

Fractyl Health ADA Investor Day

Time	Topic	Presenter
6:30 am - 7:00 am	Breakfast	
7:00 am - 7:10 am	Overview of Fractyl Health	Harith Rajagopalan, MD PhD Co-Founder and CEO of Fractyl Health
7:10 am - 7:25 am	What's Next In Metabolic Disease Treatment?	David D'Alessio, MD Chief, Division of Endocrinology and Metabolism Duke University
7:25 am - 7:40 am	Revita® and Rejuva® Pipeline Updates	Timothy Kieffer, PhD CSO of Fractyl Health
7:40 am - 7:45 am	Fractyl Health Progress, Milestones	Harith Rajagopalan, MD PhD Co-Founder and CEO of Fractyl Health
7:45 am - 8:00 am	Q&A	

Addressing the major unmet need in obesity

Differentiated, substantial opportunity with multiple near-term catalysts

Obesity: 100M in US with obesity today[1]

GLP-1 drugs have transformed the treatment landscape

Weight maintenance has emerged as the new, significant unmet need

Revita: potentially offers long-term weight maintenance after GLP-1

Weight maintenance data expected starting in Q4 2024

T2D Pivotal study topline readout expected mid-2025

Rejuva: potential remission of metabolic disease via pancreatic gene therapy

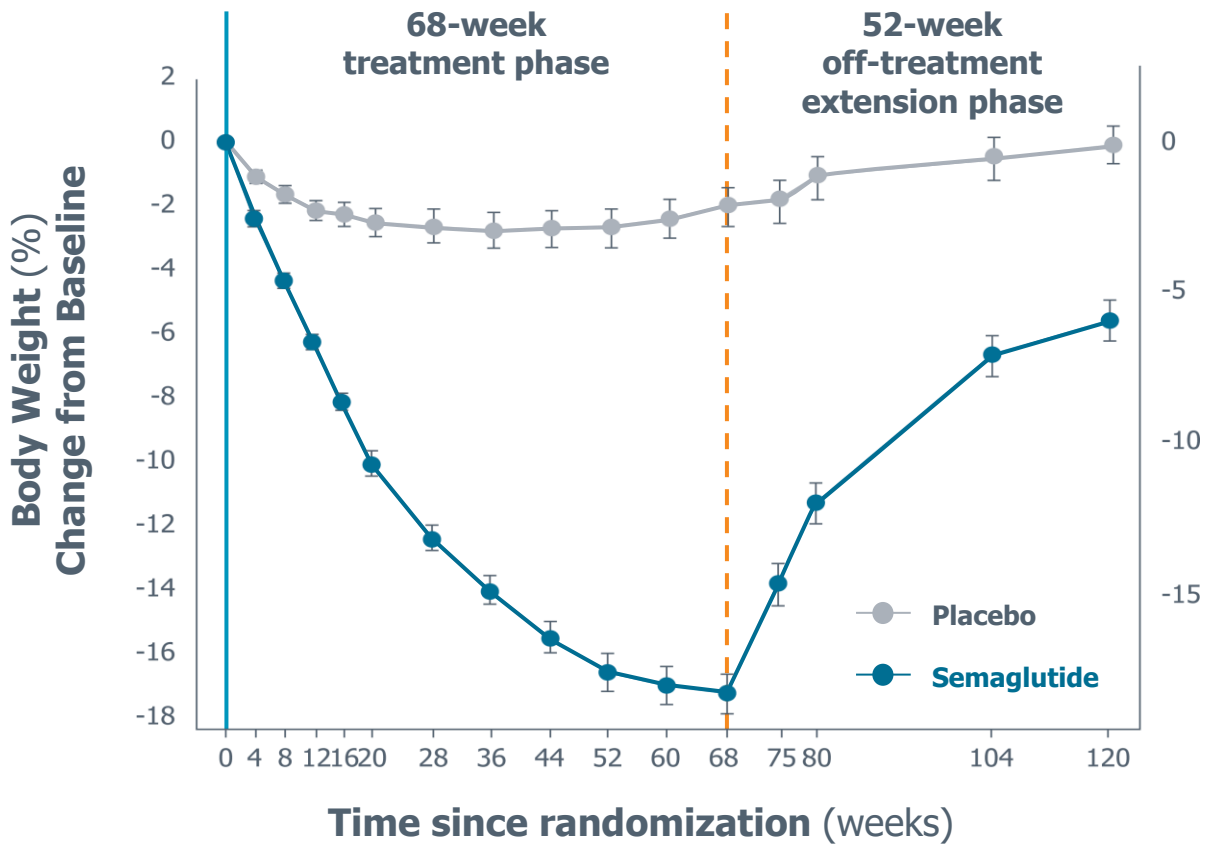
Candidate nomination for obesity planned H2 2024

FIH study for T2D planned H1 2025

1. CDC

Weight rebound after GLP-1 drug discontinuation[1]

Rapid worsening of fat mass, blood sugar, CV risk factors



> **One year after withdrawal …participants regained two-thirds of their prior weight loss…**

John P H Wilding et al
Weight regain and cardiometabolic effects after withdrawal of semaglutide: The STEP 1 trial extension[1]

1. Wilding JPH, Diabetes Obes Metab.2022;24:1553–1564 (Funded by Novo Nordisk)

GLP-1 drugs have a persistence problem

BCBS data show 50% GLP-1 drug discontinuation within 3 months

Private insurer survey of ~170K unique GLP-1 drug users for weight loss from January 2014 to December 2023[1]

Only 42% of users still on therapy at 12 weeks of follow up

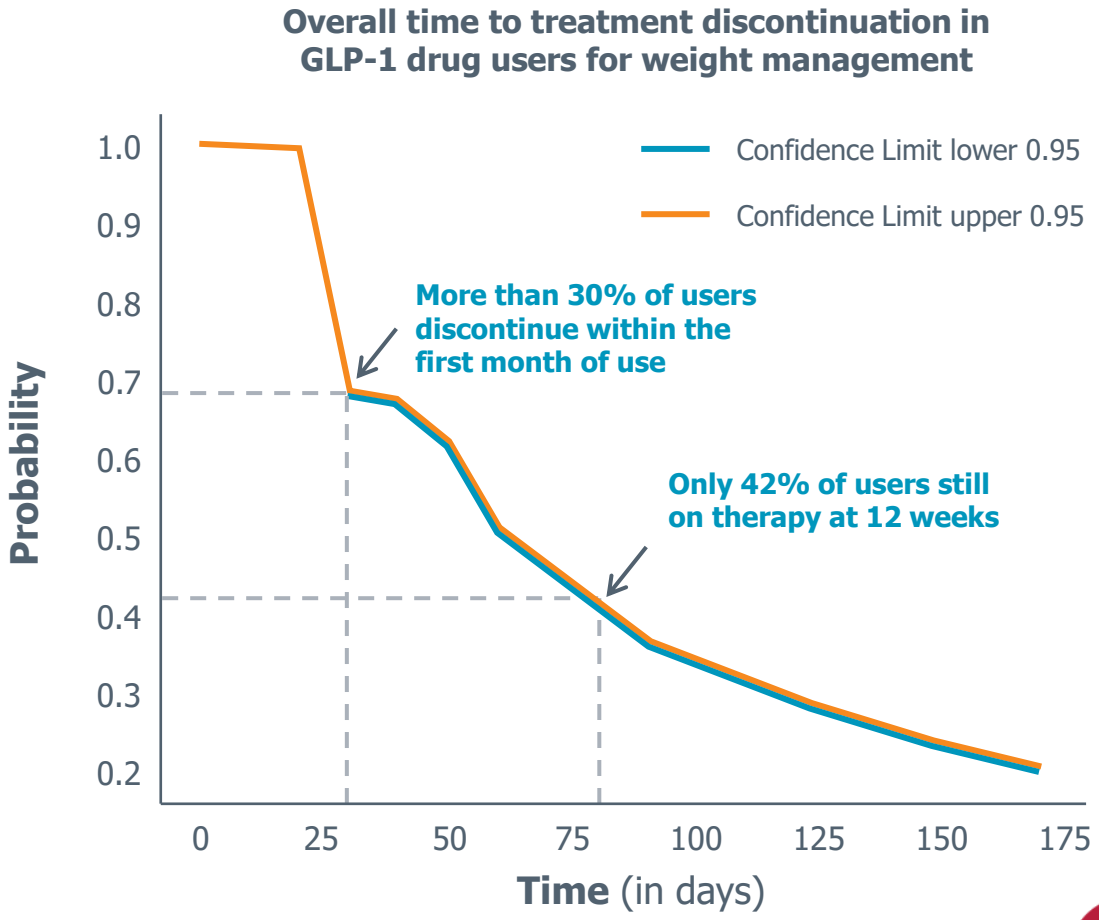
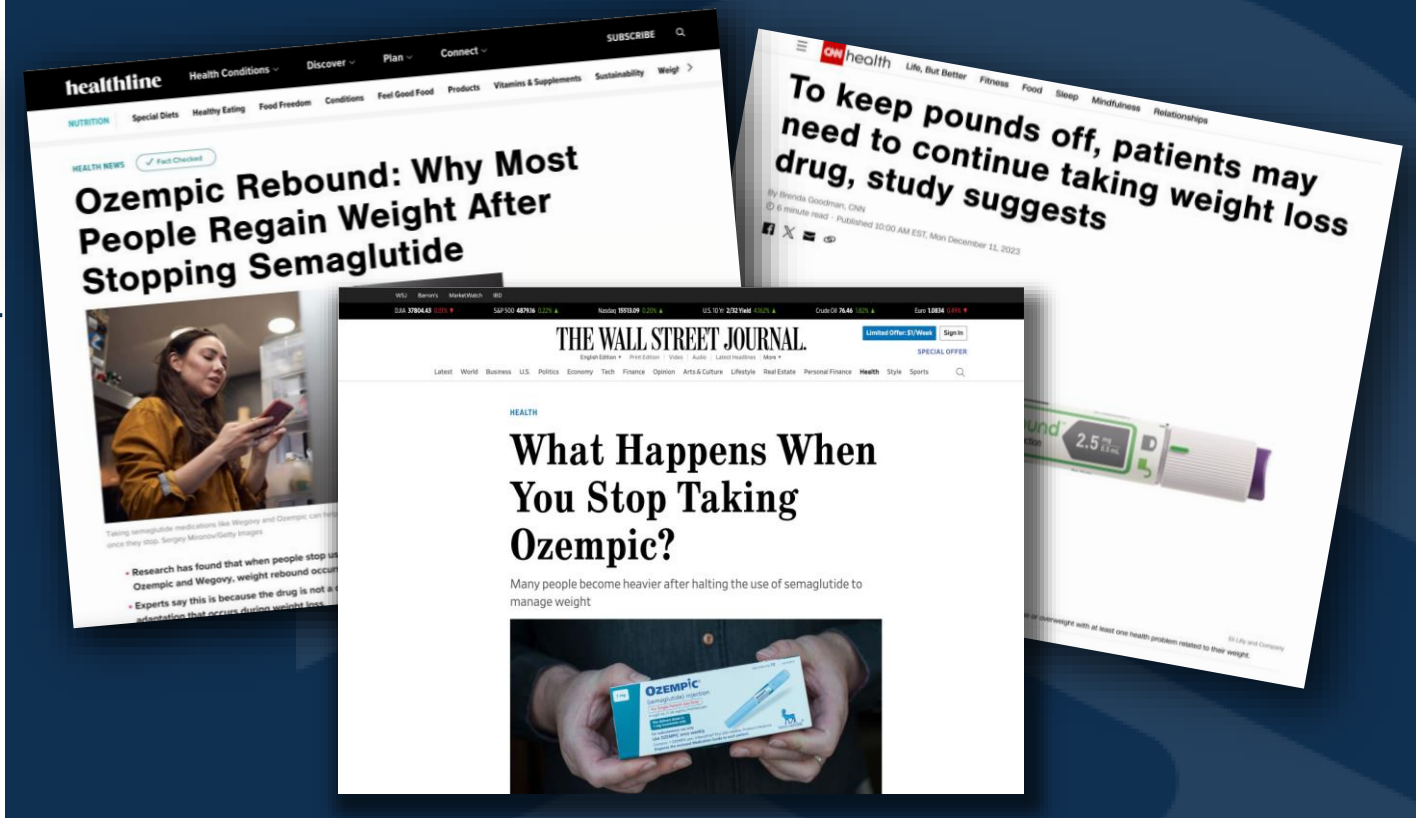


Figure adapted from Blue Health Intelligence, Issue Brief May 2024. 1. Blue Health Intelligence, Issue Brief May 2024. BCBS=Blue Cross Blue Shield, GLP-1RA=glucagon-like peptide 1 receptor agonist, PCP=primary care physician

Today's GLP-1 Therapies: Unprecedented Market Successes with Significant Limitations

Leading to the Key Question Today: How to Prevent Weight Rebound?



Fractyl's potential solutions to prevent and reverse obesity & T2D

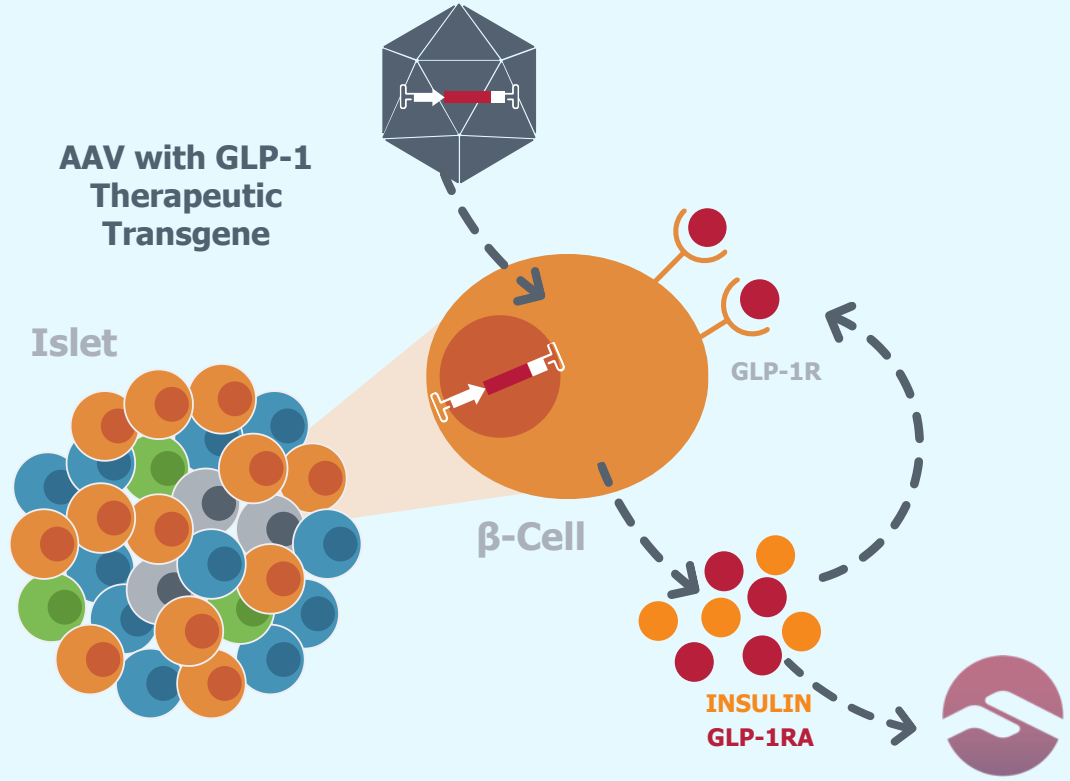
Revita and Rejuva: targeting root cause of metabolic disease

Revita

Targeting **weight maintenance and glucose control**

Rejuva

Targeting **remission of obesity and T2D**



Revita Clinical Program

Key Program Updates

Update on REMAIN-1 pivotal study

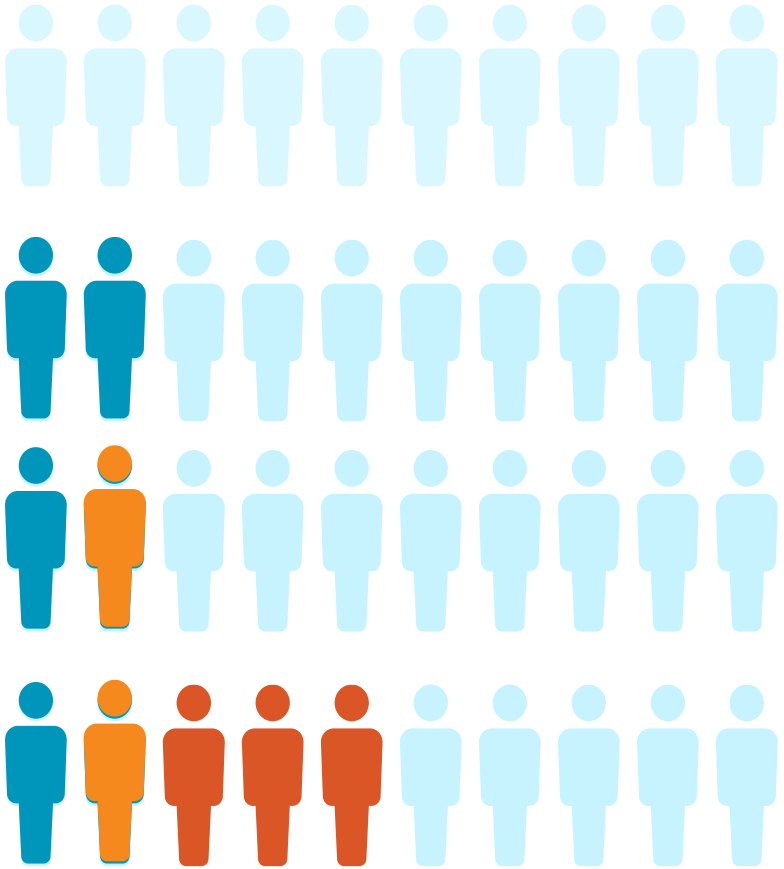
Accelerating our Revita weight maintenance opportunity

"I have been religiously taking a GLP-1 for years and I myself am looking for an option to get off!"
- US Endocrine KOL

- REMAIN-1 assesses Revita's ability to prevent weight regain after GLP-1 drug discontinuation
- Received FDA approval for REMAIN-1 pivotal study at the end of Q1 2024 (earlier than anticipated)
- Enthusiastic support from KOL physicians, PIs, and patients to address this unmet need
- Anticipate study initiation in Q3 2024 with open label REVEAL-1 weight maintenance data starting in Q4 2024 for people on GLP-1 drugs who need to stop therapy
- **Adding a planned mid-point data analysis in Q2 2025 in REMAIN-1** – controlled data with 12 week follow up post-tirzepatide discontinuation

Millions of US patients initially express interest in GLP-1s

Millions more do not achieve durable benefit from these agents



100 million people with obesity in the US today who may benefit from GLP-1 drugs[1]

Up to 20% have already tried GLP-1 drugs with CAGR up to 40%[2-3]

> 50% who have started GLP-1s discontinue within one year[4]

2/3rds who are initially interested in GLP-1 drugs lose interest when informed about risk of weight regain[5]

1. CDC 2. KFF Health Tracking Poll May 2024 3. TD Cowen estimates 4. Polonsky et al. *Diabetes Ther.* 13, 175–187 (2022) 5. KFF Health Tracking Poll July 2023

Who is the ideal patient with obesity for Revita?

Two distinct patient populations

PATIENTS NOT YET ON GLP-1's

Those who do not wish to start GLP-1 drugs in the first place because they do not want to be committed to chronic medical therapy

PATIENTS ALREADY ON GLP-1's

Those currently on GLP-1 drug and losing weight but need to stop due to side effects or other reasons

Updates on REVITALIZE-1

Significantly expanding the Revita T2D opportunity from a single pivotal study

- Patients **across the spectrum of T2D** therapy have expressed interested in Revita
- Received FDA approval for REVITALIZE-1 protocol amendment to **expand our patient population to all stages of T2D**
- Now anticipate REVITALIZE-1 to be a **single pivotal study** for the entirety of the inadequately controlled T2D patient population
- Lays groundwork for a PMA filing for a **potentially broad indication in US that closely resembles our prior study data, existing CE Mark, and real-world German registry experience**
- Represents an expansion of potential patients **from ~4M in US on insulin to ~25M in US** on any GLAs
- Anticipate topline REVITALIZE-1 primary endpoint data in mid-2025

GLAs = Glucose-lowering agents

REVITALIZE-1: Key protocol changes

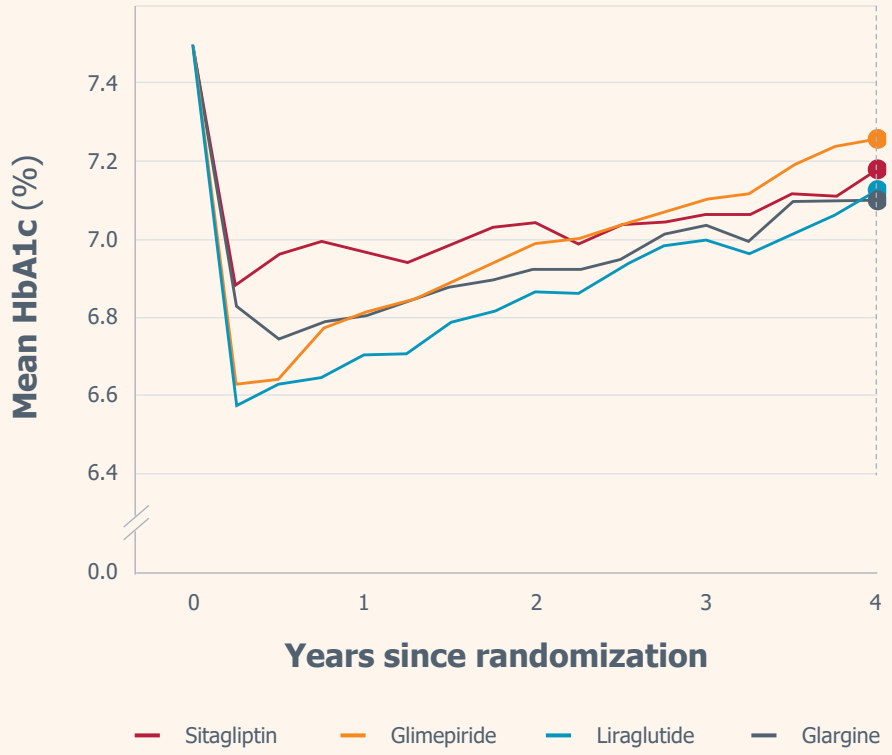
Dramatic expansion of patient population and potential indication for use

	OLD	NEW
Inclusion Criteria	HbA1c between 7.5-10% **on stable doses of 20-100 units of total daily insulin and up to 3 non-insulin GLAs**	HbA1c between 7.5-10% **on at least one glucose lowering agent (GLA)**
Proposed Indication For Use	...to improve glycemic control in adults with **inadequately controlled T2D who have preserved beta-cell function and are using insulin therapy.**	...to improve glycemic control in adults with **inadequately controlled T2D despite the use of glucose lowering agents**

Diminishing effectiveness of T2D therapies

Need more effective and durable therapies for T2D

Lack of durability of current therapies drives need for medication escalation[1]

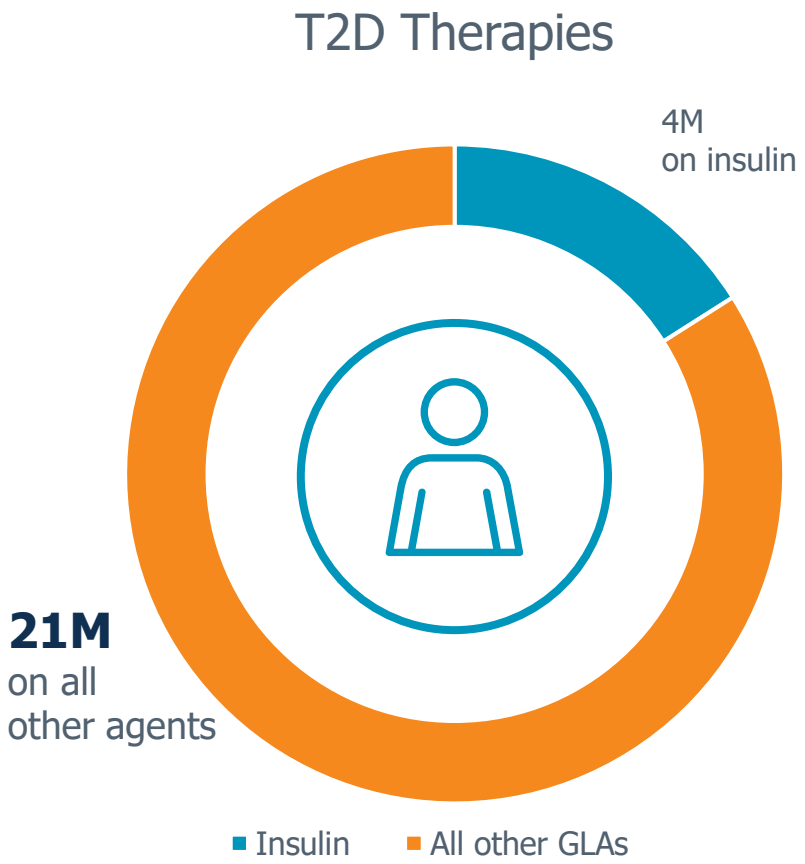


There is no drug approved for T2D today that can halt or reverse progression of disease

Adapted from: 1. GRADE Study 2022 HbA1c=hemoglobin A1c, IU=international units, OR=odds ratio, *p<0.05

Expansion of eligible T2D population in REVITALIZE-1

High numbers of patients with T2D already seeing GI physicians



Nearly 5M

Patients with T2D undergo GI endoscopies annually in US[1]

1. Compile claims database data on file

Time to try something Different: What's needed in metabolic disease treatment

David D'Alessio, MD

Duke University Division of Endocrinology

Duke

Overview

1. Despite substantial advances in science and outlays of huge amounts of money progress in treating diabetes has stalled.
2. The major driver of diabetes rates is increased body weight.
3. Good therapeutic targets exist but efficient ways to access these have been elusive.
4. The paradigm of chronic medication to manage metabolic disease is failing in its current form.

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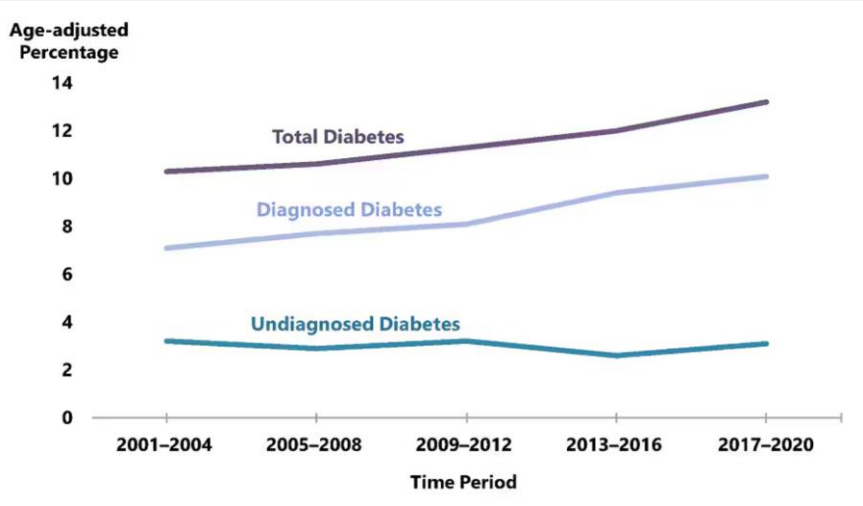
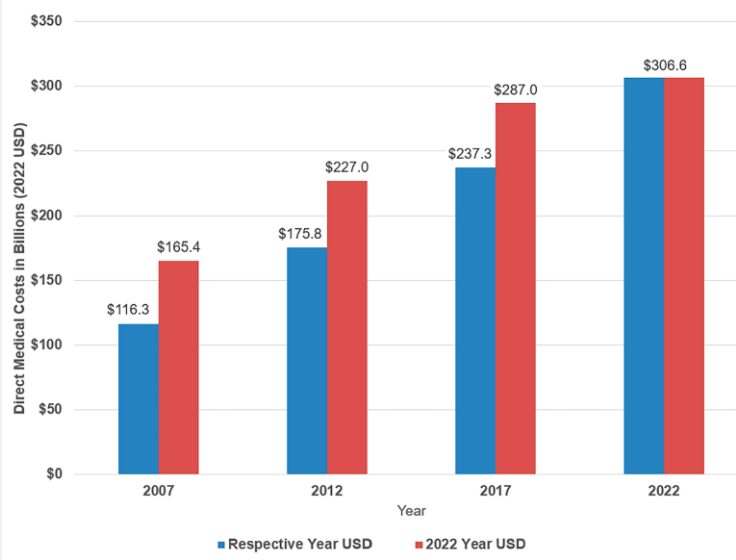
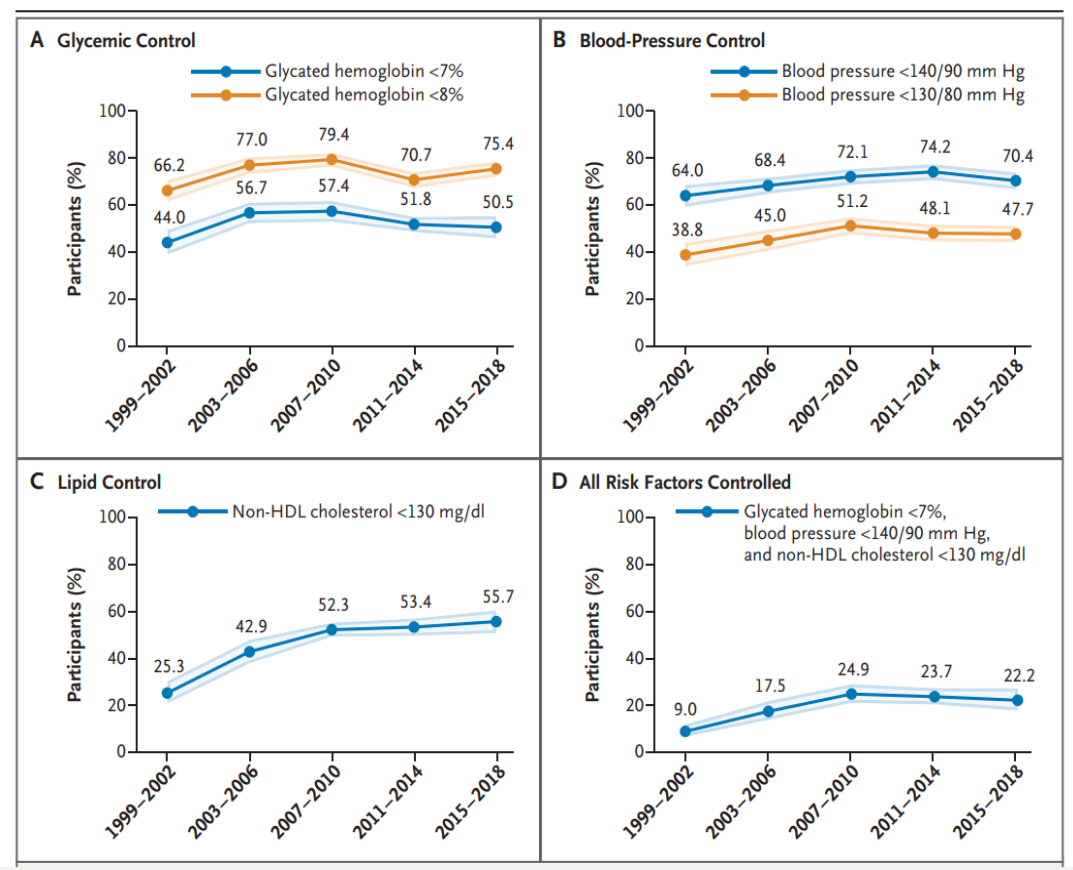
Diabetes: The state of the battle right now



CDC, May 2024



E Parker, Diab Care 2024



M Fang, NEJM 2021

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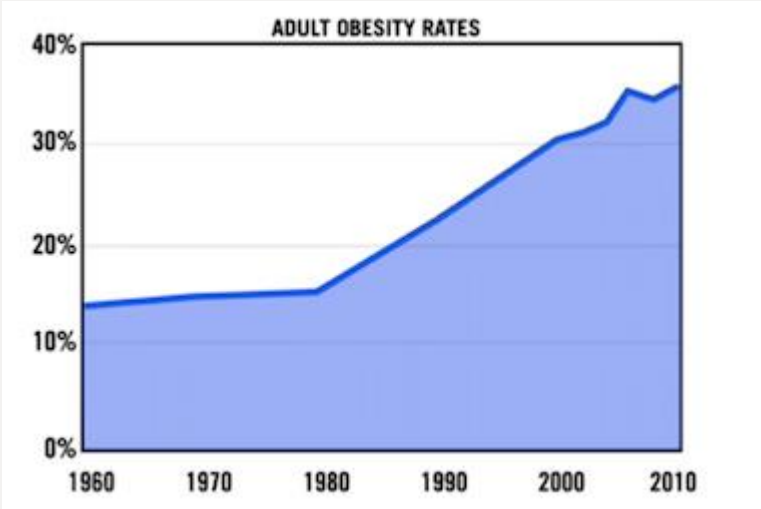
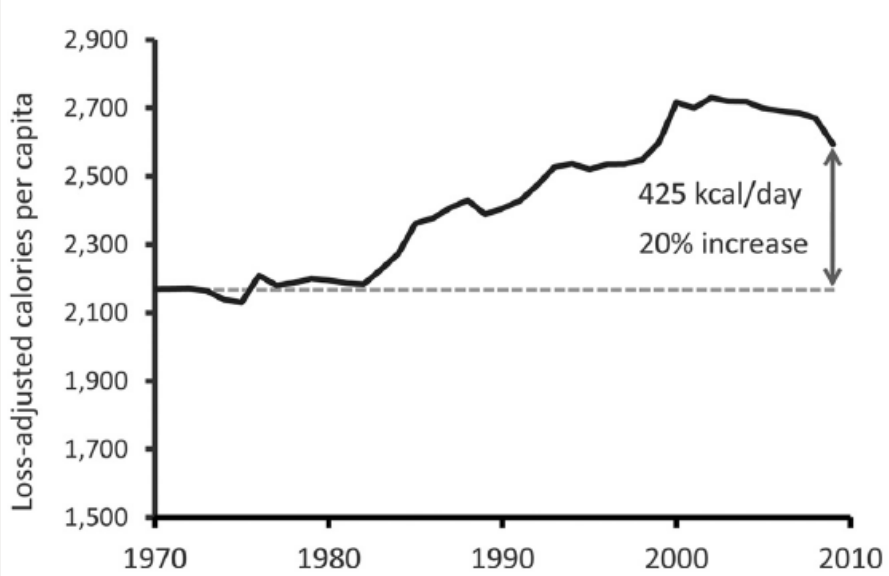
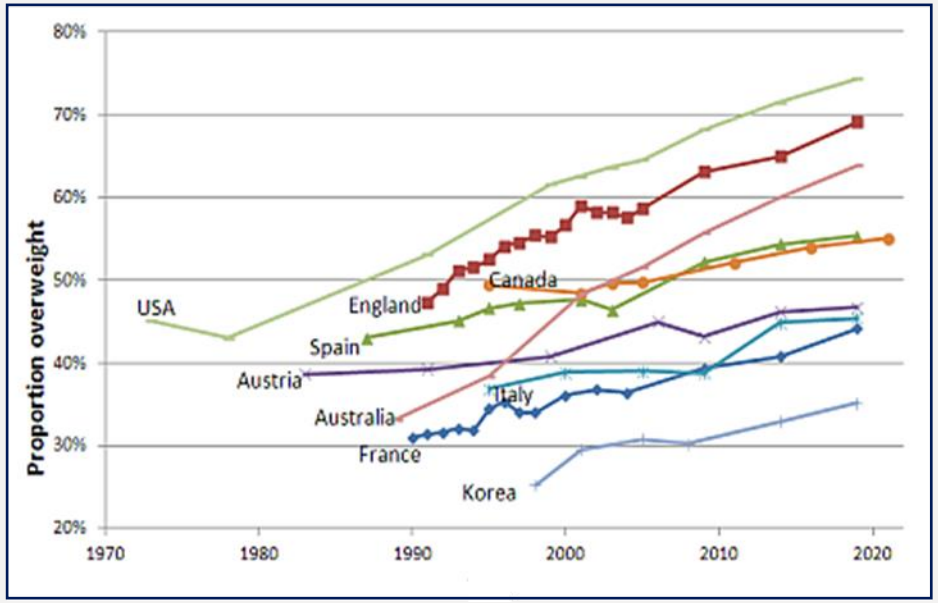
Rates of obesity have increased steadily since ~ 1980







Why do we eat more?

- Availability
- Palatability
- Marketability
- Change in behavioral patterns

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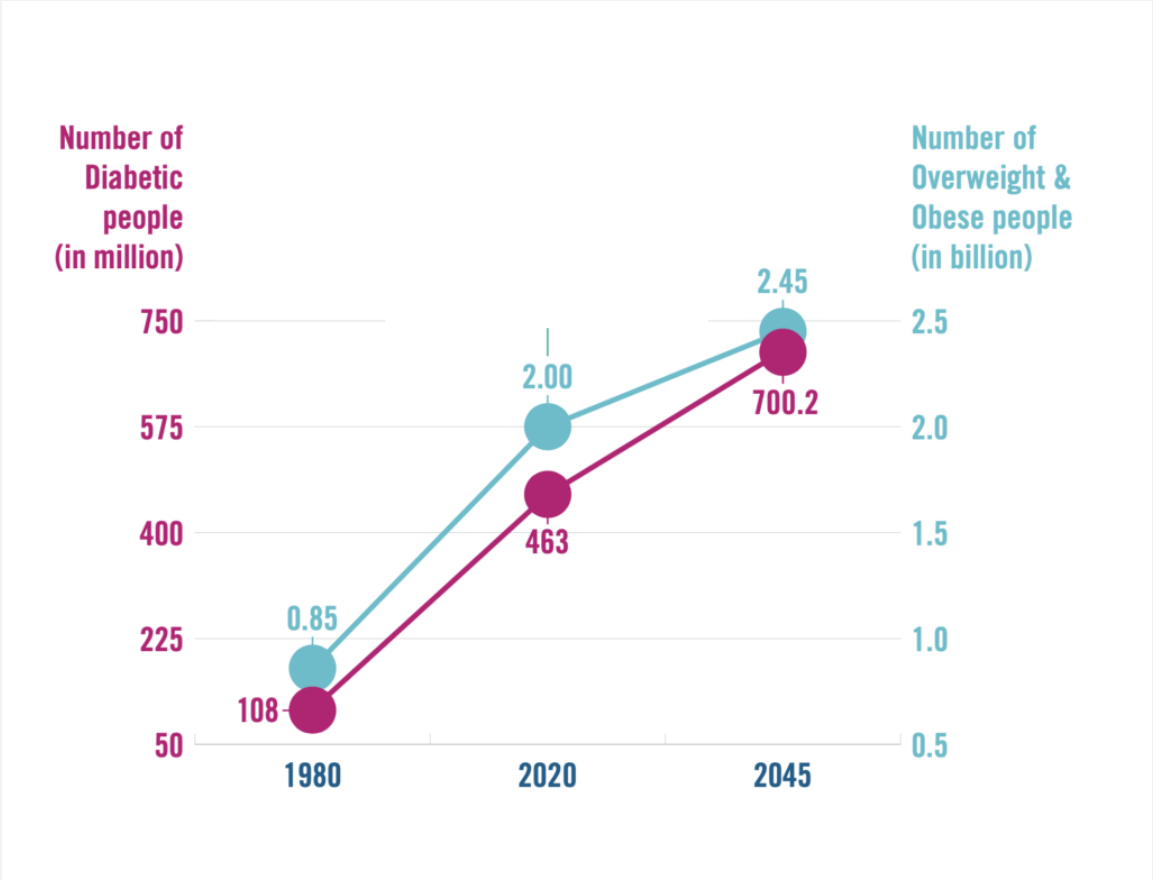
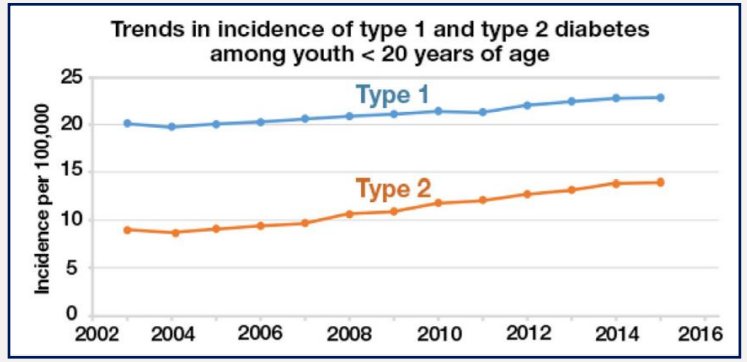
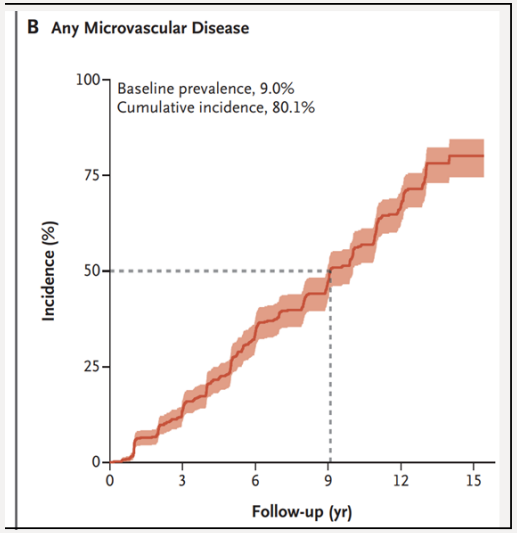
The rise in obesity has been followed by a rise in diabetes





E Buttermore, Diab Met Synd 2021



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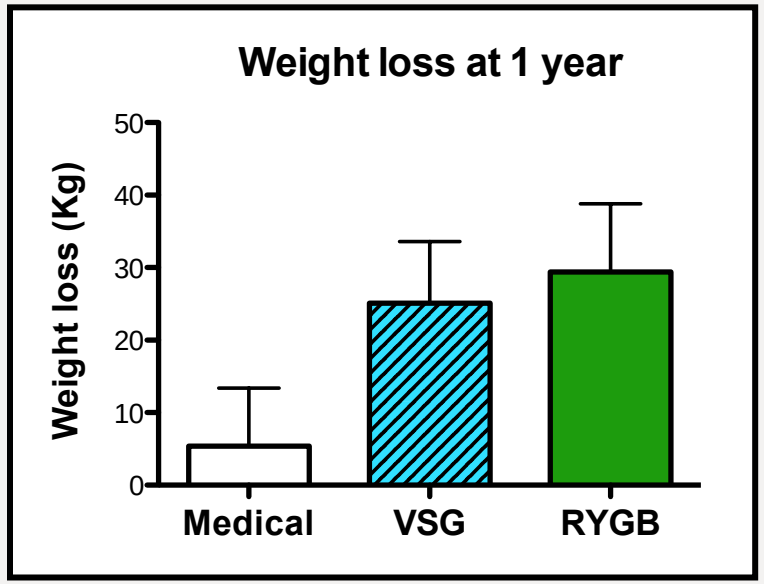
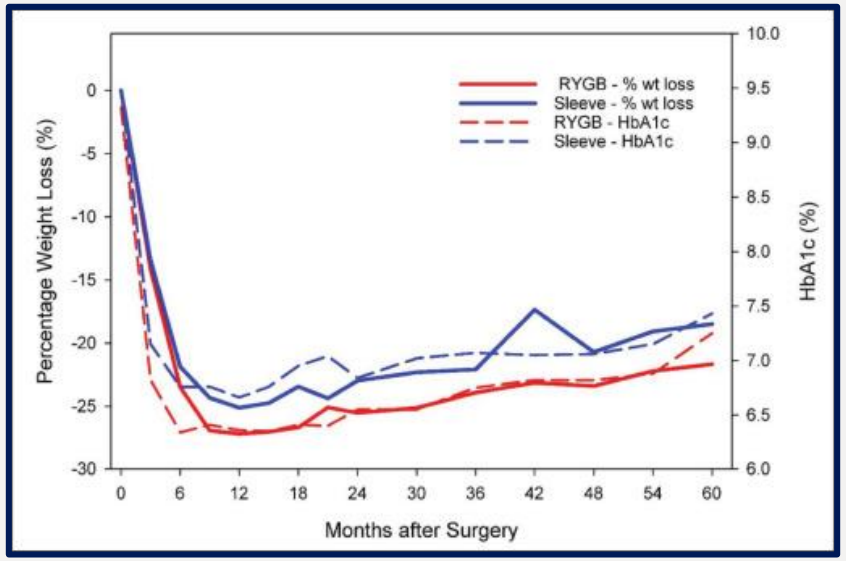
What does work is Bariatric Surgery





Short term outcomes (expected)

- 24-30% weight loss in first year
- Remission of diabetes in 50%
- Rapid improvement in sleep apnea
- Decrease hepatic steatosis
- Reduced blood pressure
- Lower cholesterol and Triglycerides

Long term outcomes (possible)

- Less CVD
- Less Cancer
- Reduced mortality

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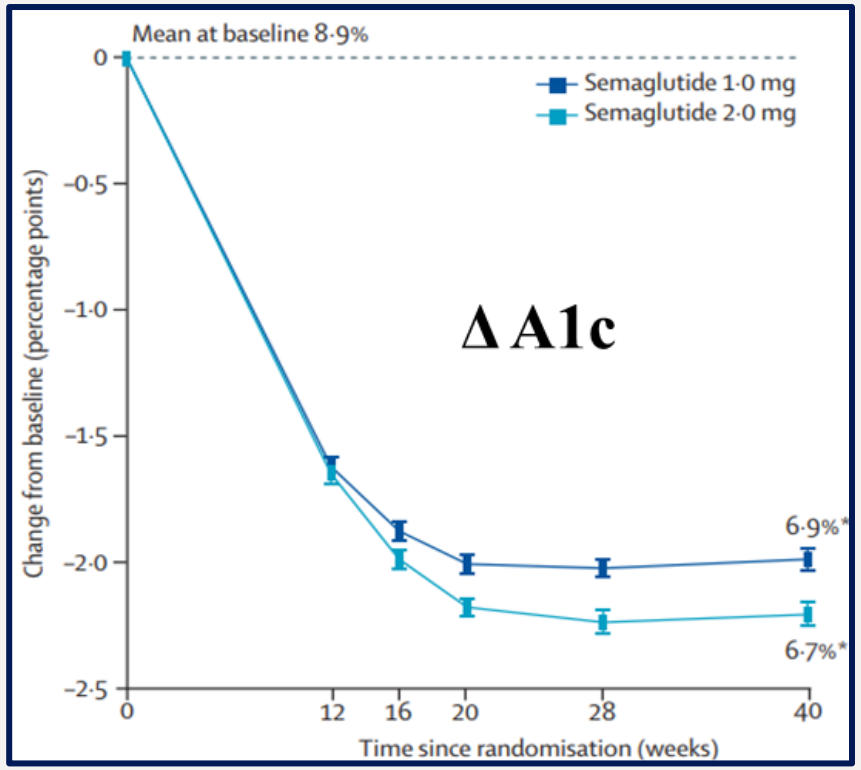
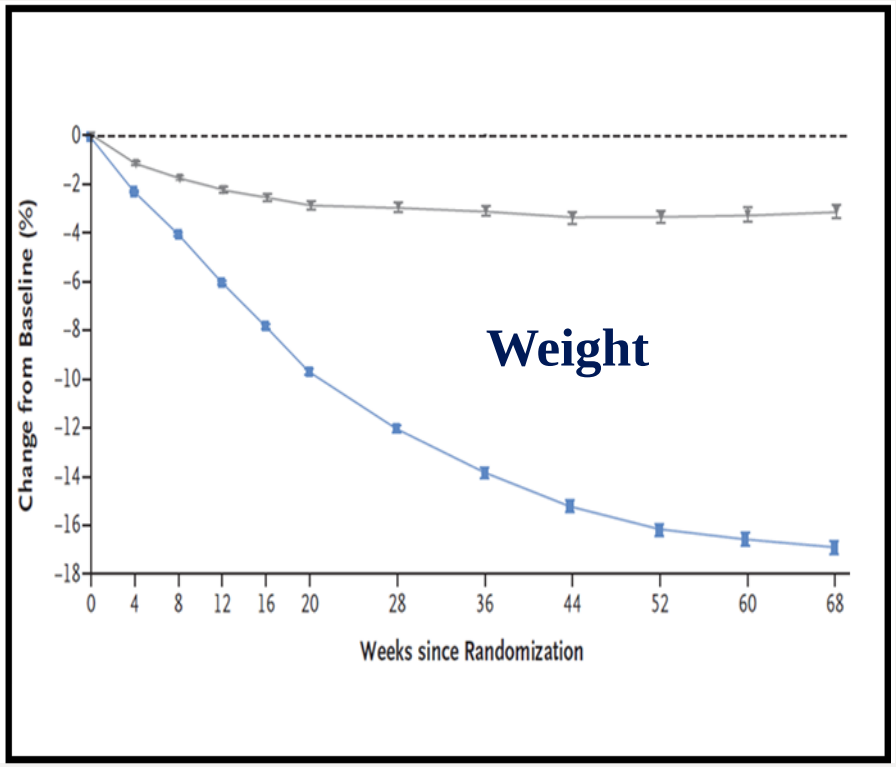
The dawn of new diabetes drugs that have meaningful impact



J Frias, Lancet 2021



J Wilding, NEJM 2021

Incretin-based drugs

- **GLP-1R system**
- **Glucose lowering**
- **Satiety signaling**
- **Potent benefit:risk**

Long acting, injectable incretin receptor agonists:

- **Promote weight loss that approaches surgery in efficacy**
- **Ameliorate many of the co-morbidities of obesity**
- **Remain under-developed with potential for even greater effects**

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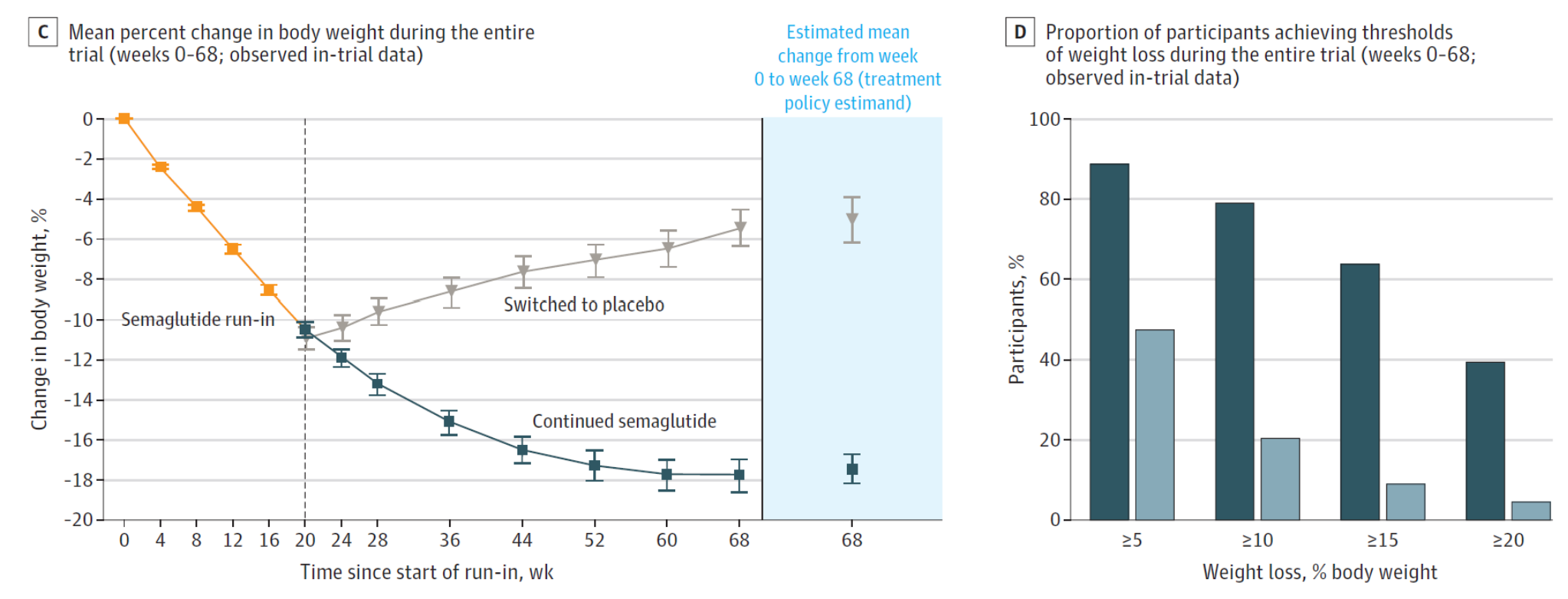
The effect of semaglutide requires continuous treatment



D Rubina, JAMA 2021

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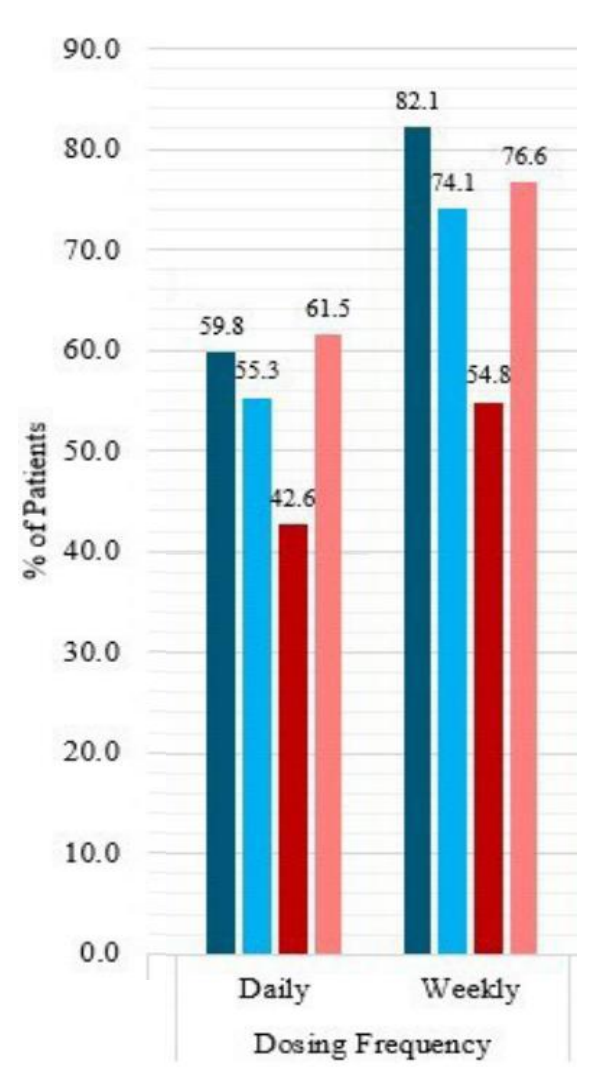
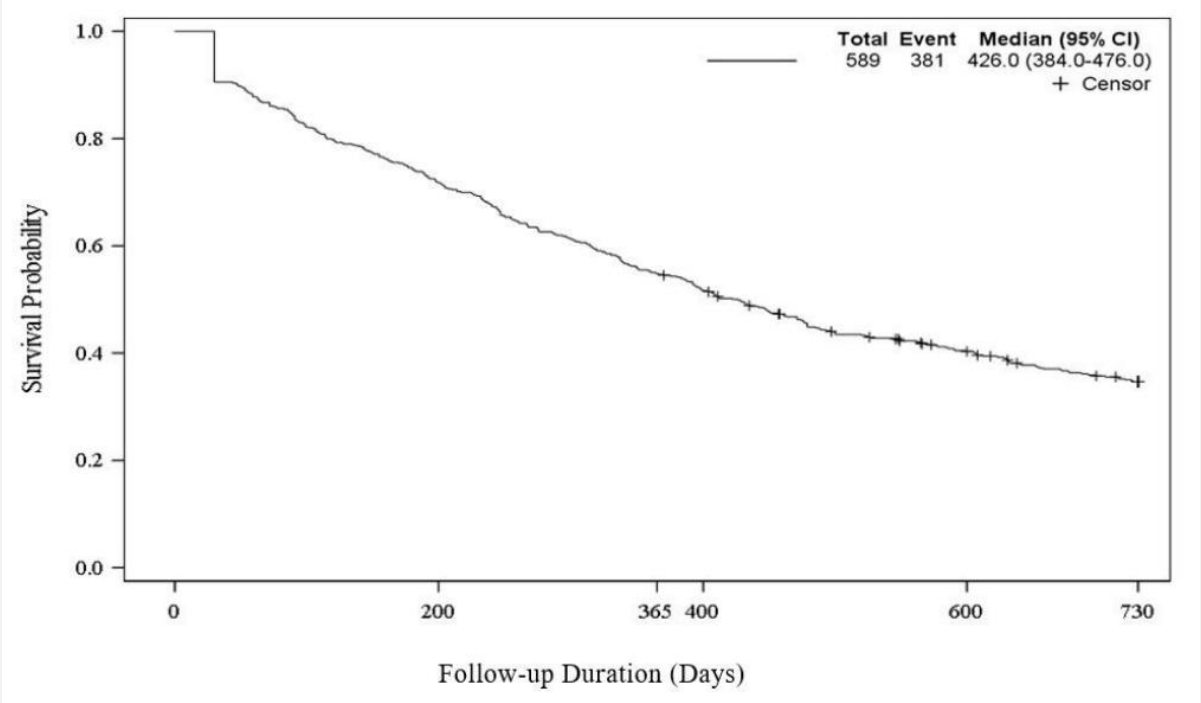
Adherence to GLP-1RA is poor despite potent treatment effects





T Weiss, BMJ Diab, 2022

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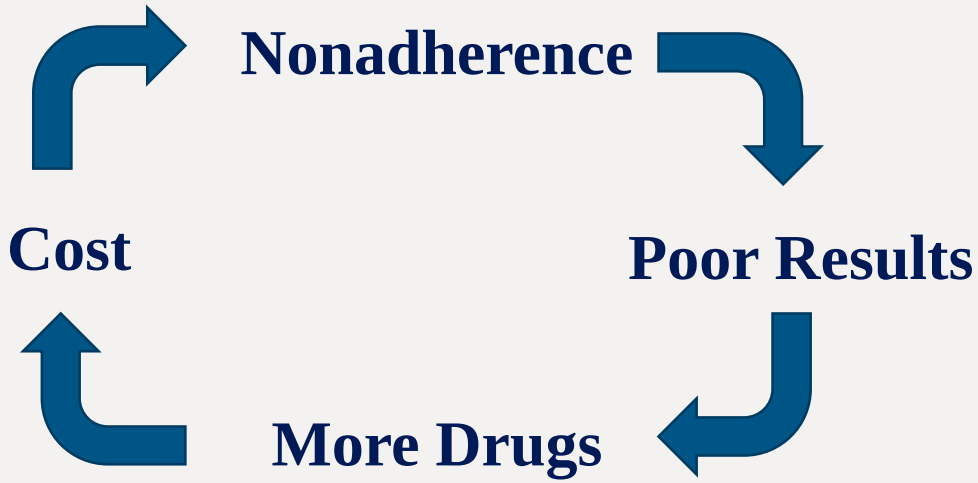
Adherence as the primary driver of diabetes control

Diabetic patients take 40-50% of what they are prescribed



Factors contributing to drug adherence

- Socio-economic
- Health care provider/System
- Condition/Co-morbidity related
- Therapy related
- Patient related

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What will it take to win the war?

1. Leverage potent mechanisms
2. Decrease the burden of treatment on patients so they can adhere with their regimens
3. Consider costs up-front in the development process
4. Expand access

Duke

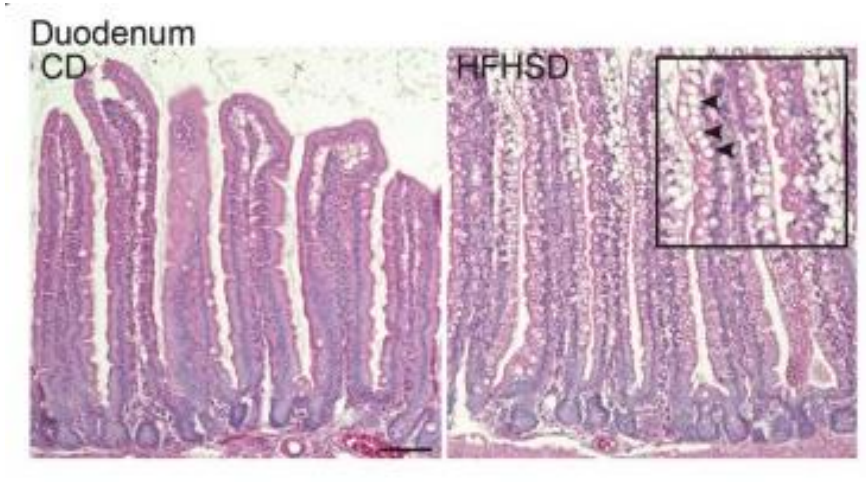
Revita Updates

Timothy Kieffer, PhD

Chief Scientific Officer, Fractyl

Gut dysfunction is a root cause of obesity & T2D[1]

Altered metabolic setpoint caused by high fat and sugar diets[2]



High fat and high sugar diets cause structural and functional changes to the gut lining

Chronic high fat and high sugar diets cause gut dysfunction → **Gut dysfunction alters gut-brain signaling[1-2]** → **Altered metabolic setpoint drives obesity and T2D[2]**

[1]Aliluev et al Nat Metab. 2021 3:1202-1216 [2]Duca et al Cell Metab. 2015 22:367-380 CD = Chow Diet HFHSD = High Fat High Sugar Diet

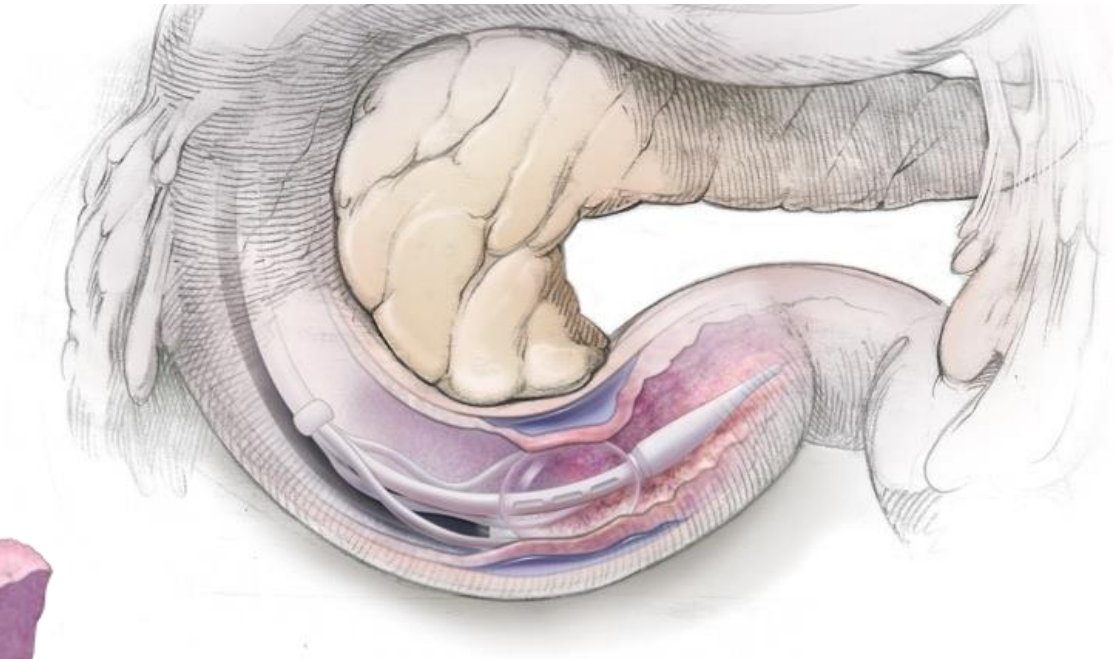
Revita targets gut dysfunction

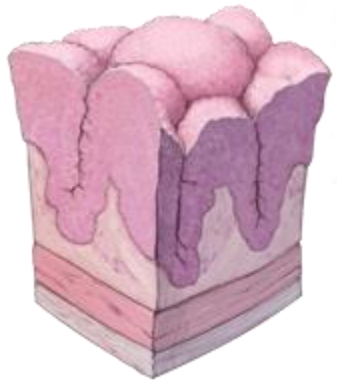
First potential opportunity for a durable metabolic reset[1-4]

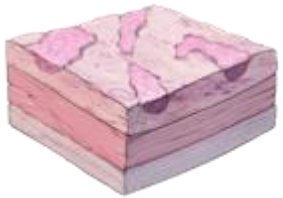
Outpatient endoscopic procedural therapy

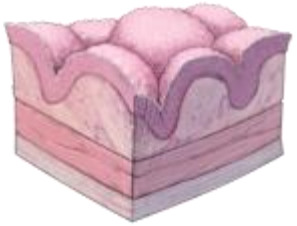
Clinical trials in > 300 participants

2-year durable improvements in weight and glucose[4-10]









Dysfunctional → **Ablated** → **Regenerated**

1. Mah AT et al. Endocrinology. 2014 155:3302-3314. 2. Mao J et al. Diabetes. 2013 62:3736-3746. 3. de Moura EGH et al. Endosc Int Open. 2019 7:E685-E690. 4. Haidry RJ, et al. Gastrointest Endosc. 2019 90:673-681.e2. 5. van Baar ACG, et al. Endosc Int Open. 2020 8:E1683-E1689. 6. Rajagopalan H, et al Diabetes Care. 2016 39:2254-2261. 7. van Baar ACG, et al. Gut. 2020 69:295-303. 8. Mingrone G, et al. Gut. 2022 71:254-264. 9. van Baar ACG, et al. Gastrointest Endosc. 2021 94:111-120.e3. 10. van Baar et al. Diabetes Res. Clin. Pract. 2022 184:109194

Revita weight maintenance results

Pooled weight loss data in T2D including overweight participants[1]

Patient population

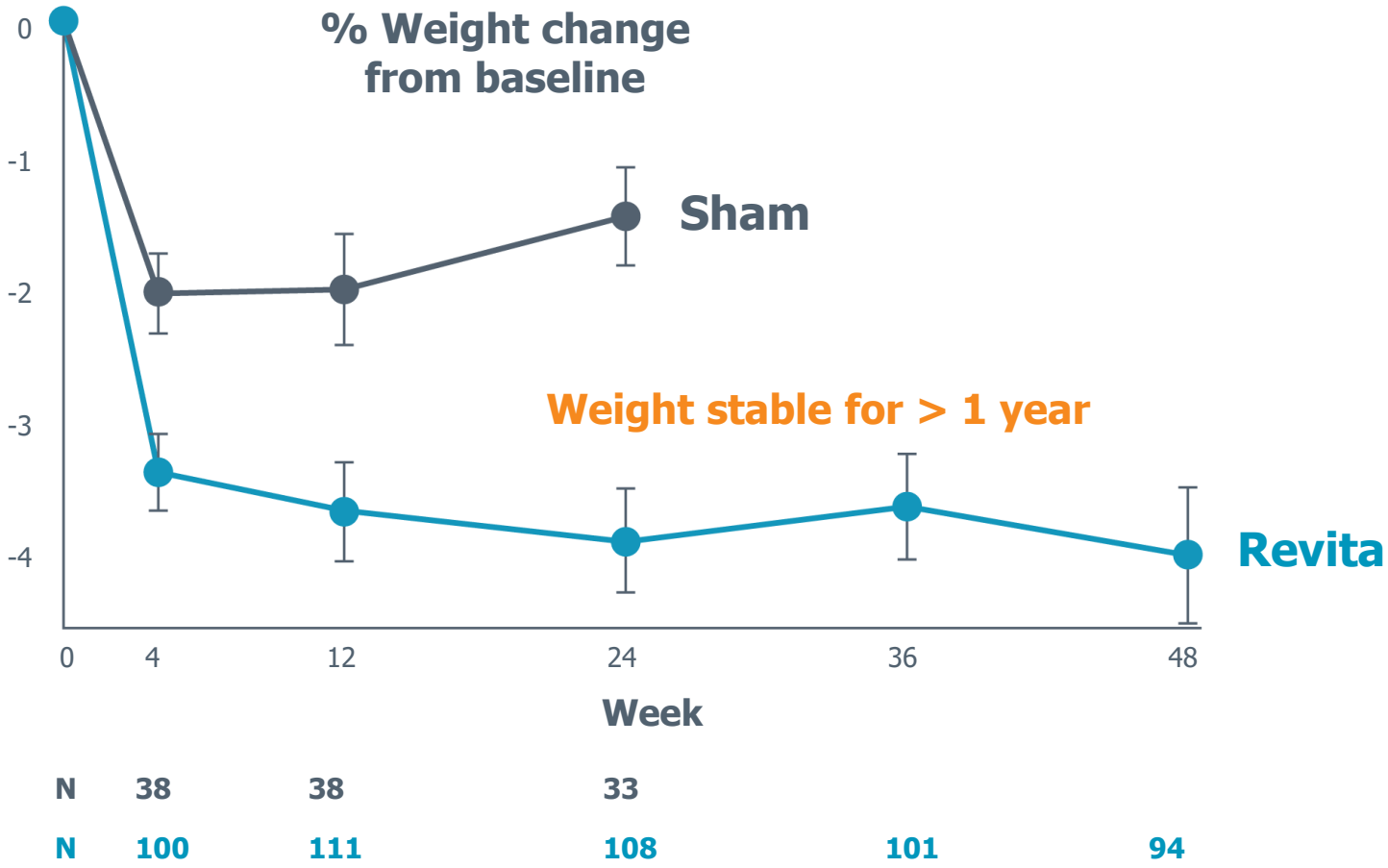
Patients with advanced T2D on multiple GLAs

Baseline Demographics

Baseline 93 kg (BMI 31.1)

HbA1c 8.3%

T2D duration 10 years



Ozempic 1 mg demonstrated similar body weight loss (~ 5% at wk 30) in similar T2D patients[2]

1. Fractyl Health, Data on File. 2. Sorli C et al. The Lancet Diabetes & Endocrinology 2017; 5(4)251-260. ; we have not conducted any head-to-head studies of Revita with Ozempic

Post-market registry ongoing in Germany

Weight loss and glucose control in real world experience[1]

Patient population

Patients with T2D on at least 1 GLA at baseline

Baseline demographics

62 years age
64% male
14 years duration T2D
BMI 32.1 kg/m^2

Anticipated timing

Quarterly open label data updates

	Baseline n=14 **Median** (min,max)	**6 Month n=14** **Median** (min,max)
Weight (kg)	**111** (66,139)	**102** (62,127)
HbA1c (%)	**9.2** (7.3,12.8)	**7.6** (6.0,13.2)
FPG (mg/dL)	**153** (101,355)	**116** (79,198)

- The DMR procedure was well tolerated in registry participants with no DMR-related serious adverse events reported to date.

1. Fractyl Health, Data on File as of May 2024 NCT06256497 GLAs = Glucose Lowering Agents

Reveal-1 weight maintenance study[1]

Open label study for patients who need to stop GLP-1s

Patient population	Primary endpoint	Key secondary endpoints	Study design	Anticipated timing
Obese patients (BMI 30) without T2D and achieving at least 15% TBW loss with tirzepatide or semaglutide and cannot continue drug Up to 20 participants	Change from baseline in weight compared to historical controlled studies of GLP-1 withdrawal	Glucose, CV risk factors	Single-arm, open-label, cohort study of Revita after GLP-1 drug discontinuation Diet and lifestyle counseling throughout	**Open label study updates expected starting in Q4 2024**

TBW = total body weight. 1. Reveal-1 is an open label cohort as part of the Remain-1 pivotal IDE. Participants may either already be taking GLP-1 based semaglutide or tirzepatide and have achieved at least 15% TBW loss or will initiate tirzepatide to achieve at least 15% TBW loss before Revita

Remain-1 pivotal study in weight maintenance

Planned mid-point data analysis anticipated in Q2 2025

Patient population

Obese patients (BMI 30) without T2D and GLP-1 drug naive

At least 315 participants

Planned mid-point data analysis after 45 participants randomized and followed for 12 weeks

Co-Primary endpoints

Change from baseline in weight to week 24
and
% of Revita participants who maintain at least 5% TBW loss at week 24

Key secondary endpoints

Glucose,
CV risk factors

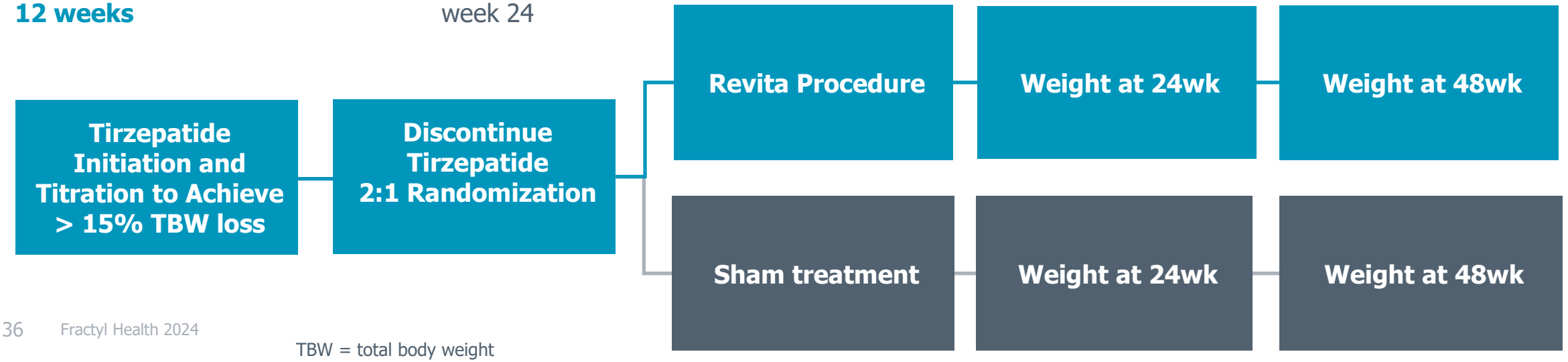
Study design

Randomized (2:1), double blind, sham controlled after GLP-1 discontinuation

Diet and lifestyle counseling throughout

Anticipated timing

Planned mid-point data analysis expected in Q2 2025



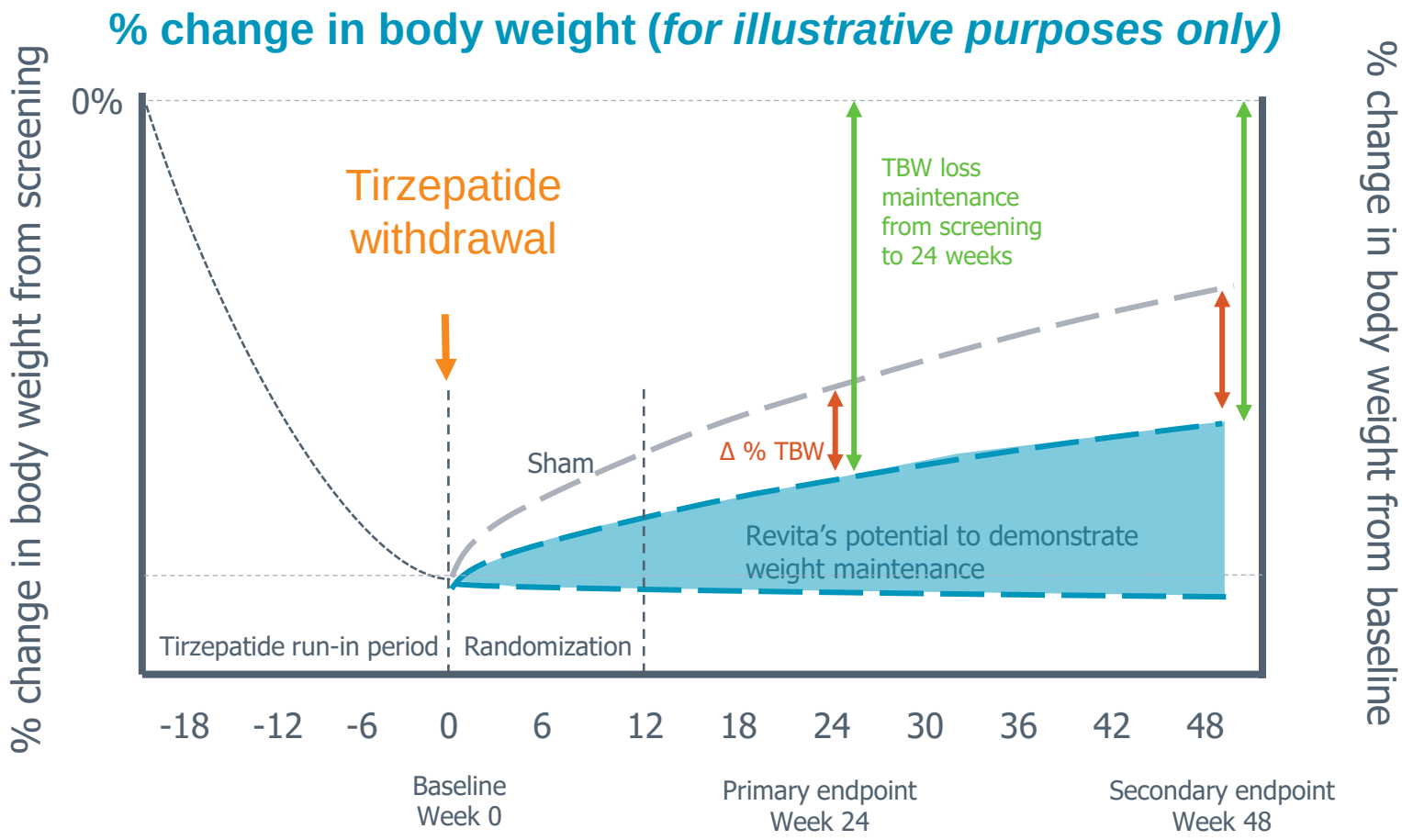
TBW = total body weight

Potential results from Remain-1 pivotal study

Revita's ability to demonstrate weight maintenance

Planned mid-point data analysis in Q2 2025

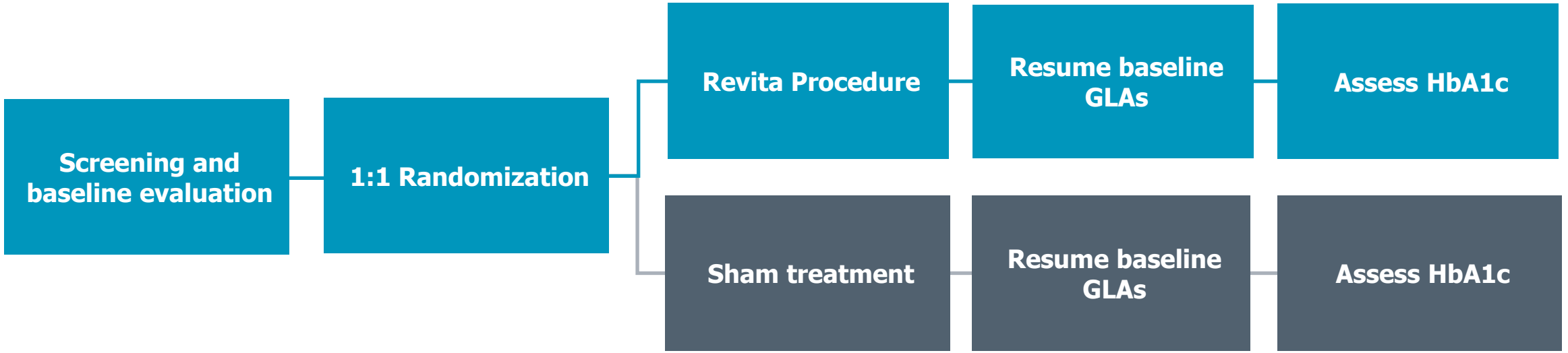
Randomized data at 12 week follow up



Revitalize-1 pivotal study underway

FDA Breakthrough Designation and CMS reimbursement support

Patient population	Primary endpoint	Key secondary endpoints	Study design	Anticipated timing
Inadequately controlled T2D (HbA1c > 7.5) despite use of at least 1 glucose lowering agent (GLA)	Change from baseline in HbA1c at 24 weeks	HbA1c targets weight loss, insulin requirement	Randomized (1:1) double blind sham controlled	**Topline data mid-2025**



Revitalize 1 Study; ClinicalTrials.gov Identifier: NCT04419779

Rejuva Updates

Timothy Kieffer, PhD

Chief Scientific Officer, Fractyl

Pancreatic Gene Therapy (PGTx) to modify islet function

Potential for durable improvement in metabolic health

GLP-1 gene therapy, targeted to pancreatic islets, may offer differentiated benefit

β-cell machinery can be leveraged to produce nutrient-stimulated hormones[1,2]

Islet cells are terminally differentiated,[3] making adeno-associated virus (AAV) suitable for durable effect

Opportunity to amplify islet GLP-1 signaling to improve β-cell health

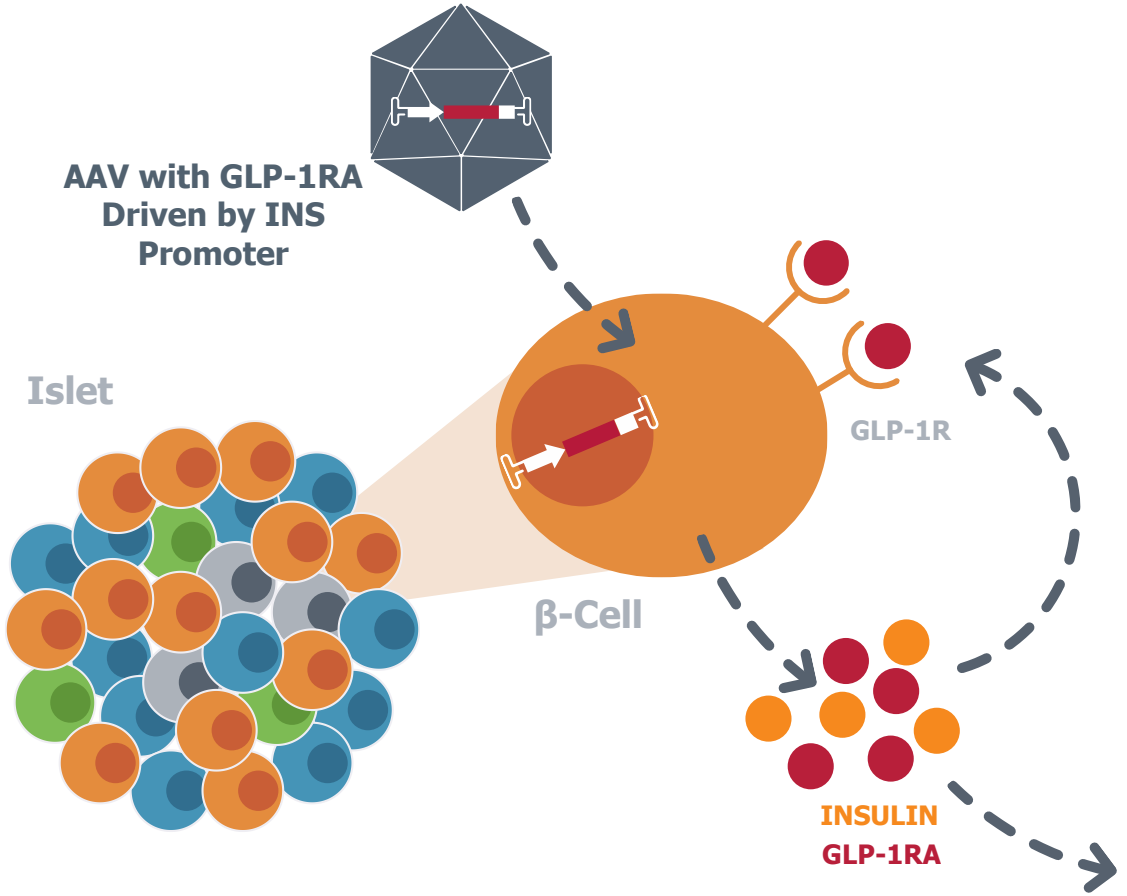
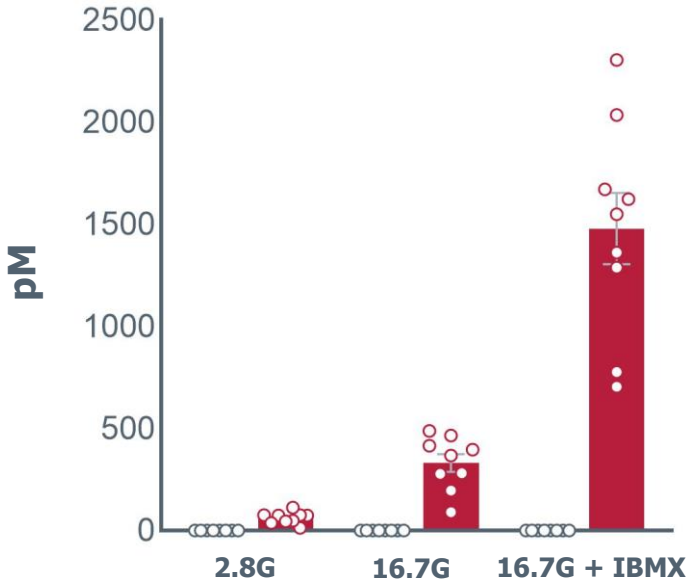


Figure adapted from Saikia et al. JCI Insight. 2021 6:e1418511. 1. Lubaczeuski et al. Keystone 2023 oral presentation. Poster no. 1025. 2. Rajagopalan et al. ADA 2023 oral presentation. Abstract no. 181-OR. 3. Perl et al. J Clin Endocrinol Metab. 2010 95: E234–E239. AAV=adeno-associated virus, GLP-1=glucagon-like peptide 1, GLP-1R=GLP-1 receptor, GLP-1RA=GLP-1R agonist, INS=insulin, PGTx=pancreatic gene therapy

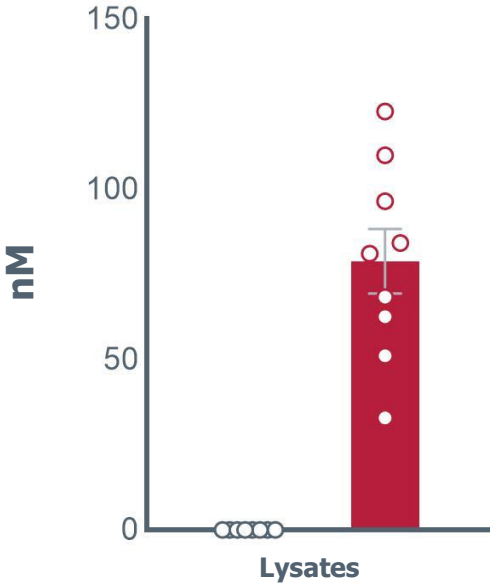
GLP-1RA PGTx secretion in isolated *db/db* islets

Glucose-dependent GLP-1RA release with ample secretory reserve

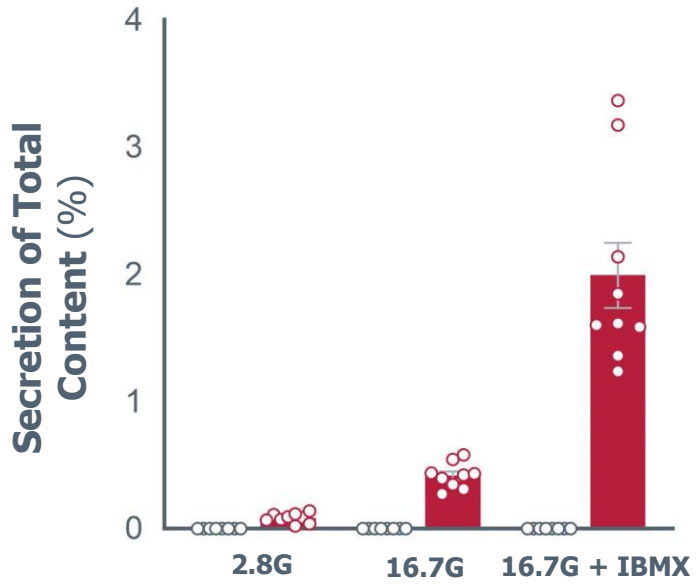
A) GLP-1RA Released



B) GLP-1RA Total Content



C) GLP-1RA Secretion (% of Total Content)



Vehicle Control GLP-1RA PGTx

Islets were isolated 9 weeks post-GLP-1RA PGTx treatment, N=3 mice/group, 15 islets/well, performed in triplicate. 2.8G=2.8mM glucose, 16.7G=16.7mM glucose, GLP-1RA=glucagon-like peptide 1 receptor agonist, IBMX=3-isobutyl-1-methylxanthine, PGTx=pancreatic gene therapy

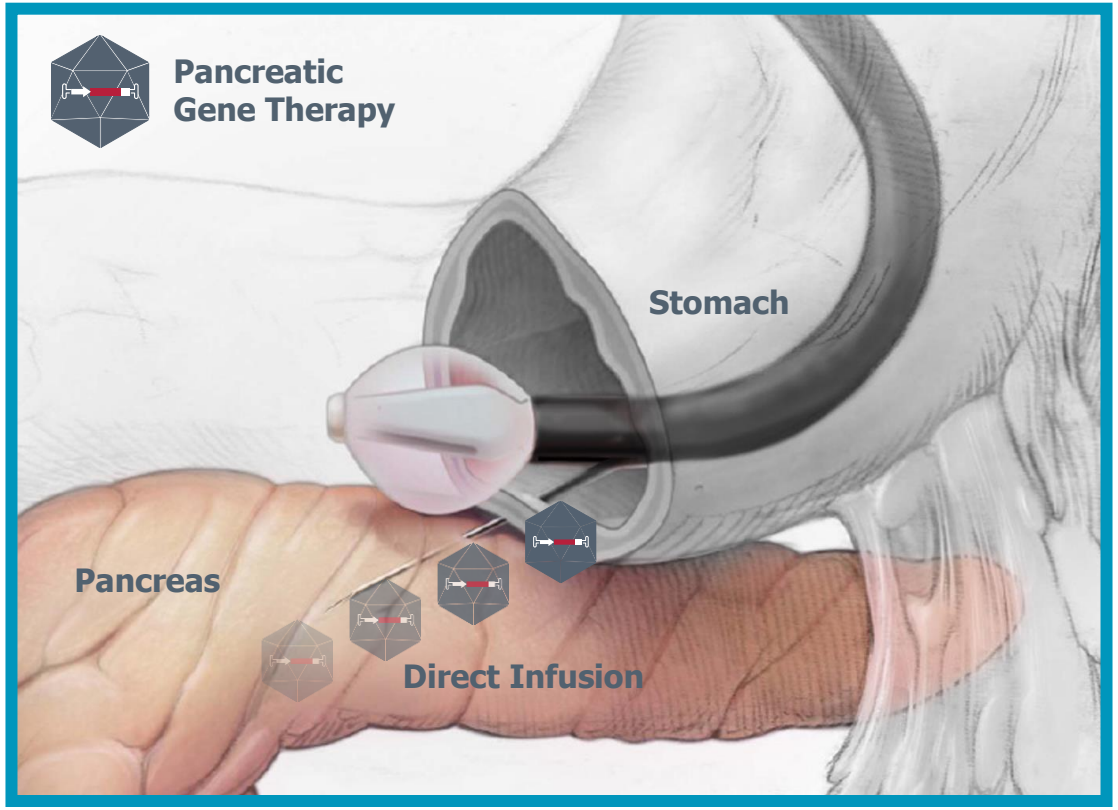
Gene therapy route of administration to pancreas

Proprietary, automated, endoscopic delivery device

Local delivery enables low viral genome dosing with limited systemic virus exposure[1]

Islets are readily accessible[2,3] via already established, routine, upper endoscopic ultrasound procedures,[4] performed in ~300K patients per year in US[5]

Procedural risk is further mitigated with device design (e.g., needle size, volume, controlled infusion rate)



Endoscopic Procedure & PGTx Delivery

1. Rajagopalan et al. ASGCT 2023 oral presentation. Abstract no. 191. 2. Docherty & Russ. Encyclopedia of Tissue Engineering and Regenerative Medicine 2019, pg. 367-374. 3. Ravi et al. Medicine (Baltimore). 2021 Apr 30;100(17):e25642. 4. Hasan & Hawes. Gastrointest Endosc Clin N Am. 2012 Apr;22(2):155-67. 5. Peery et al. Gastroenterology 2022 Feb: 162(2):621-644. PGTx=pancreatic gene therapy

Dose-dependent transduction in Yucatan Pig Model

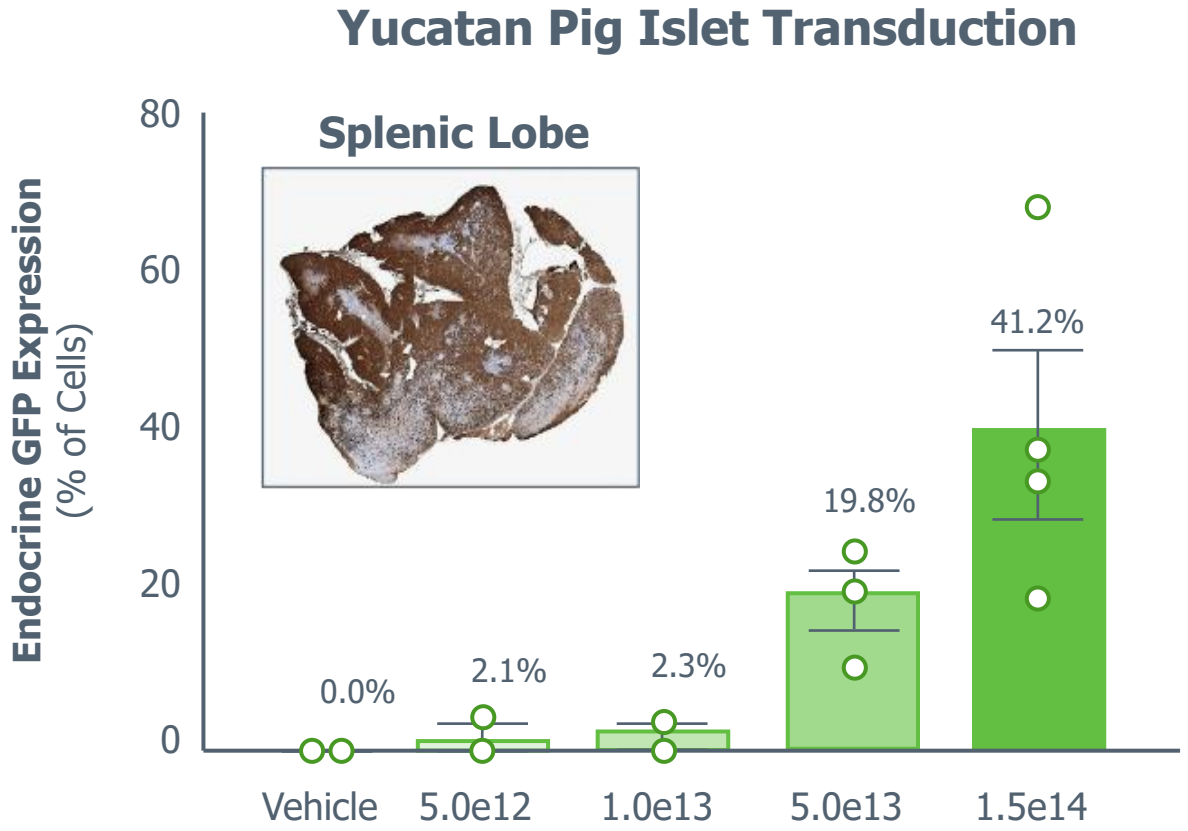
Local delivery effectively and reliably targets islets

Yucatan pig model **anatomy similar to humans**[1]

Dose-dependent AAV-GFP expression in targeted pancreatic lobe[2,3]

>60 animals treated with 100% technical success

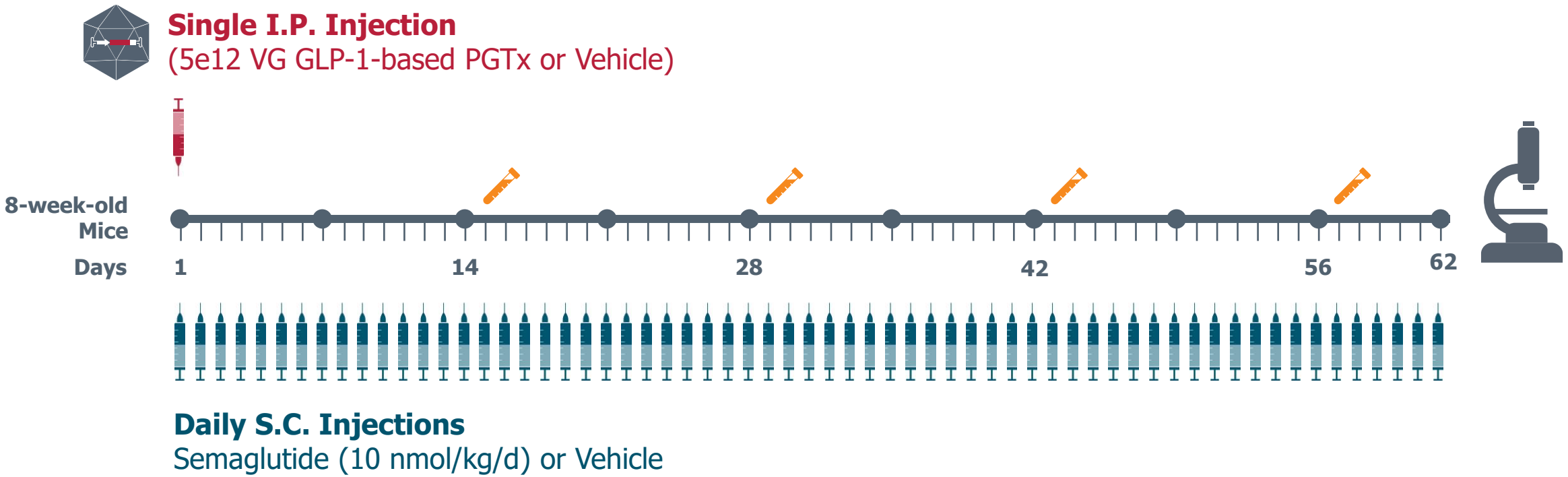
No adverse safety signals to date (e.g., pancreatitis)



Mean ± SD shown; n=2-4 per group. 1. Walters and Prather. Mo Med. 2013 May-Jun;110(3):212-5. 2. Thompson et al. DDW 2023 poster presentation. Control no. 3862948. 3. Rajagopalan et al. ASGCT 2023 oral presentation. Abstract no. 191. AAV=adeno-associated virus, GFP=green fluorescent protein

RJVA-001 prototype* vs. semaglutide

Design of POC efficacy study in db/db mouse (standard T2D model)

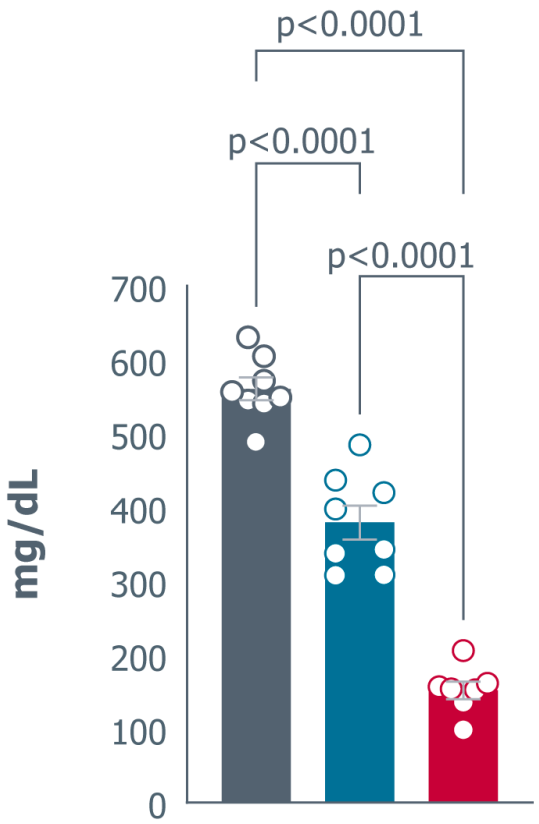


GLP-1=glucagon-like peptide 1, GLP-1RA=glucagon-like peptide 1 receptor agonist, I.P.=intraperitoneal, PGTx=pancreatic gene therapy, S.C.=subcutaneous, T2D=type 2 diabetes, VG=vector genomes

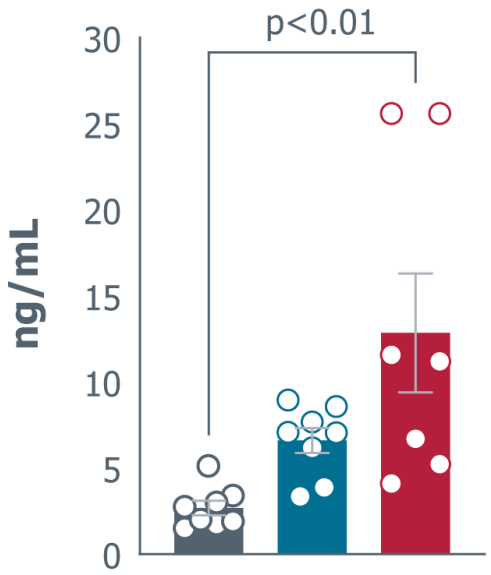
Glucose-lowering efficacy in *db/db* murine model

GLP-1RA PGTx improves glucose, insulin, and weight vs. daily semaglutide

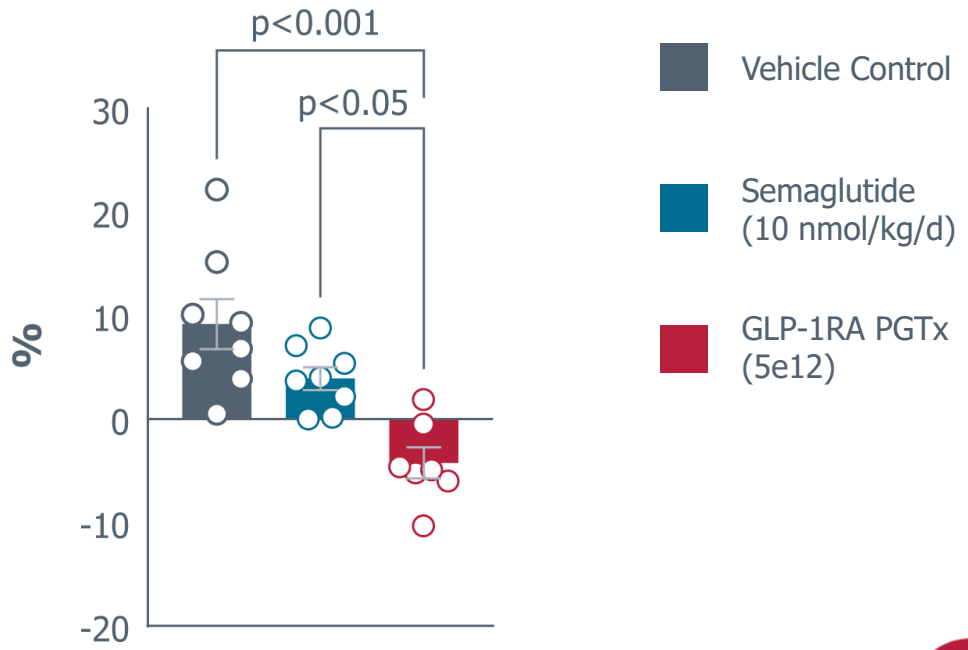
A) Fasting Blood Glucose



B) Fasting Plasma Insulin



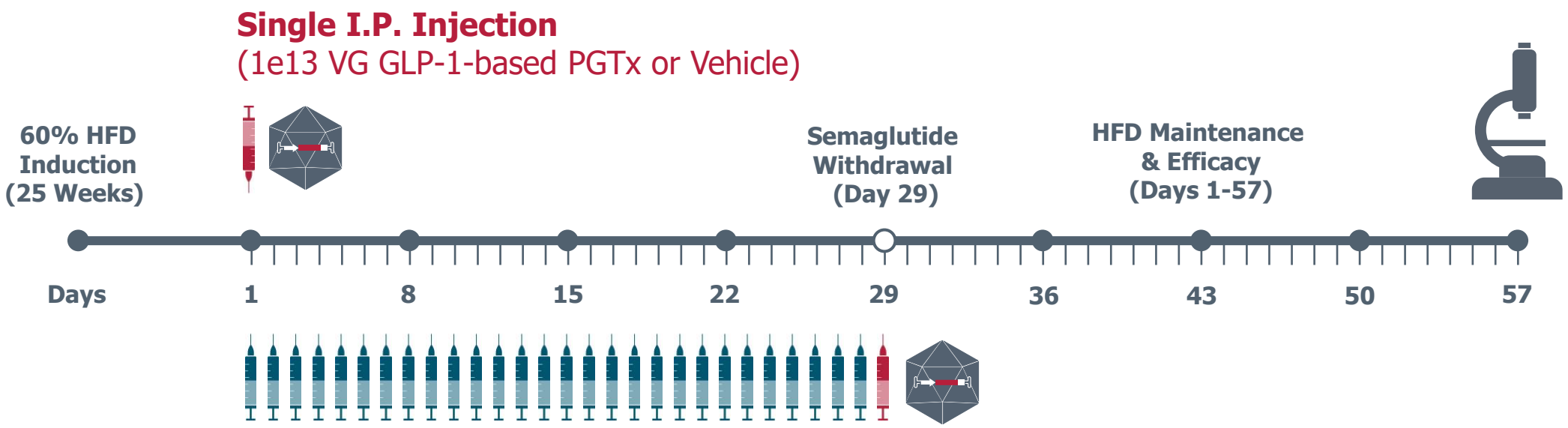
C) Body Weight Change from Baseline



Mean ± SEM shown; n=7-8 per group, day 29 shown, Rajagopalan et al. DDW 2024 oral presentation. Abstract no. 4029196. GLP-1RA=glucagon-like peptide 1 receptor agonist, PGTx=pancreatic gene therapy

RJVA-001 prototype* vs. semaglutide

Design of POC efficacy study in DIO mouse (standard obesity model)

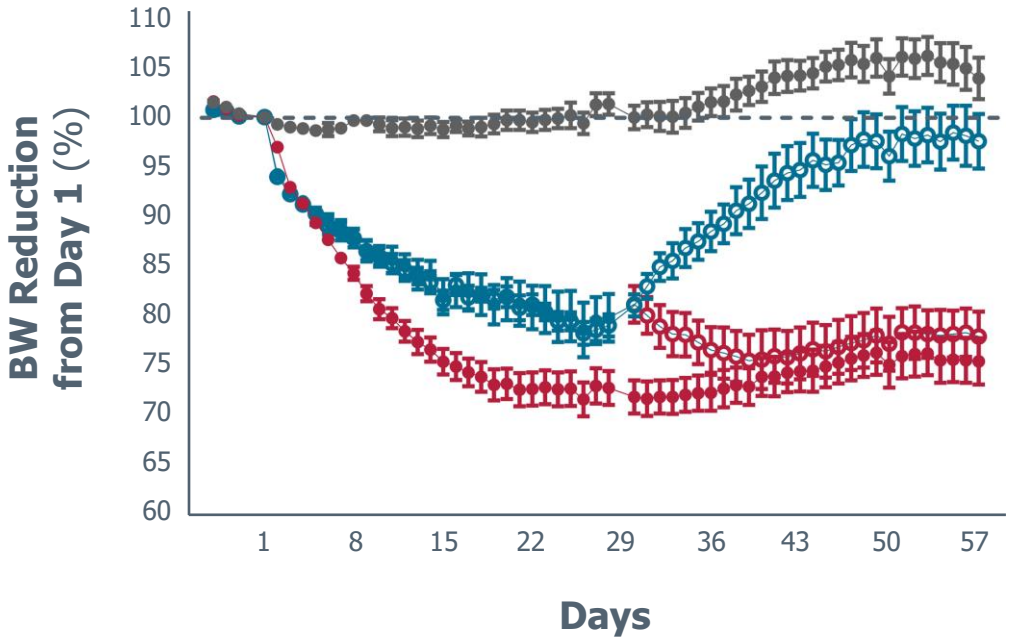


Fitzpatrick AL et al. WCIRDC 2023 oral presentation; AAV=adeno-associated virus, BW=body weight, BWL=body weight loss, DIO=diet-induced obesity, GLP1=glucagon-like peptide 1, GLP1RA= GLP1 receptor agonist, HFD=high fat diet, INS=insulin promoter, I.P.=intraperitoneal, PGTx=pancreatic gene therapy, S.C.=subcutaneous

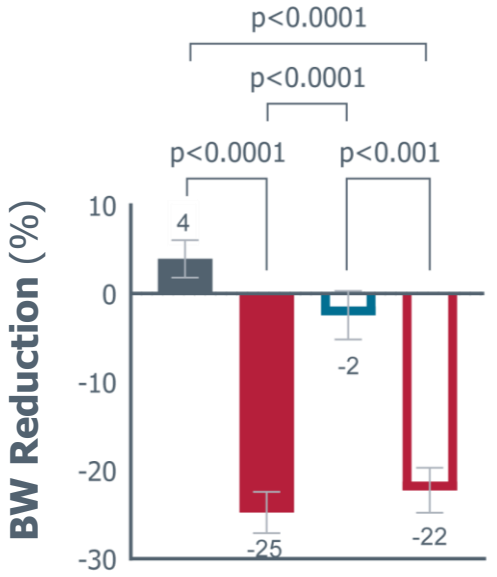
RJVA-001 prototype* vs. semaglutide

Weight loss and food intake in DIO mouse model

A) Change in BW Over Time



B) End of Study BW Change



Vehicle Control

Sema (10 nmol/kg/d)

GLP-1RA PGTx (1e13 VG)

Sema Withdrawal + Vehicle

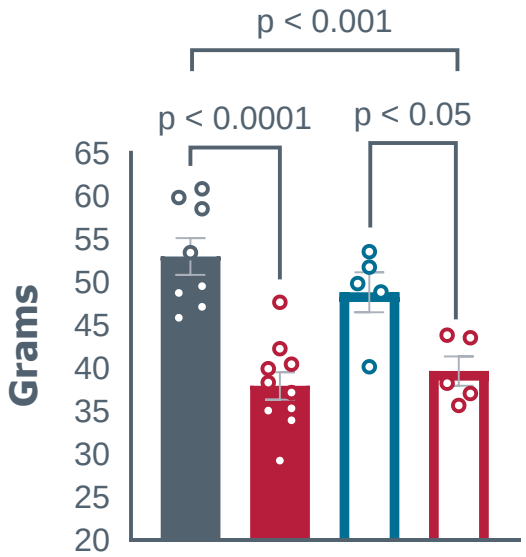
Sema Withdrawal + GLP-1RA PGTx (5e12 VG)

Mean ± SEM shown; n=5-10 per group. Fitzpatrick et al. WCIRDC 2023 oral presentation. Abstract no. 0077. BW=body weight, DIO=diet-induced obesity, GLP-1RA=glucagon-like peptide 1 receptor agonist, PGTx=pancreatic gene therapy, Sema=semaglutide, VG=vector genomes

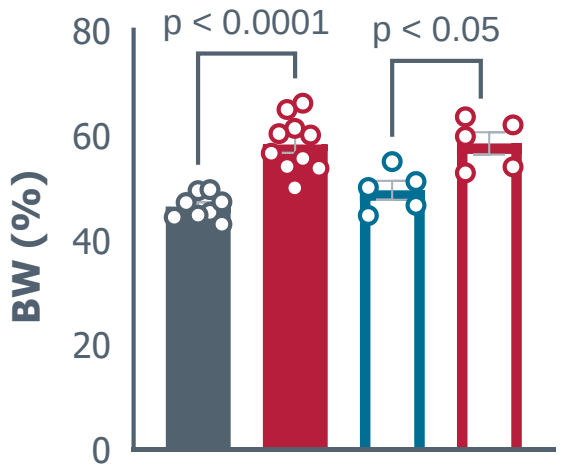
Body composition change in DIO murine model

Preservation of lean mass: body weight loss primarily from fat mass

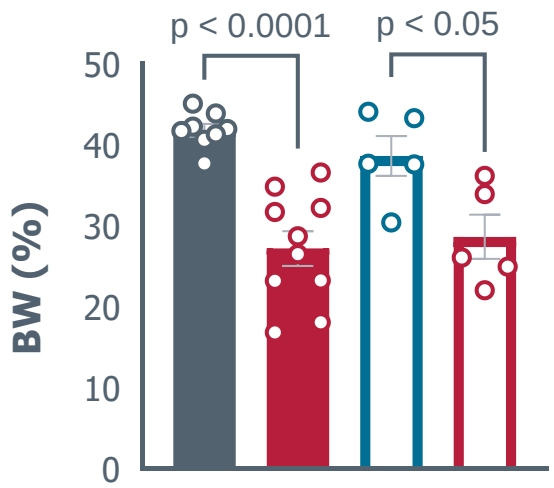
A) Body Weight



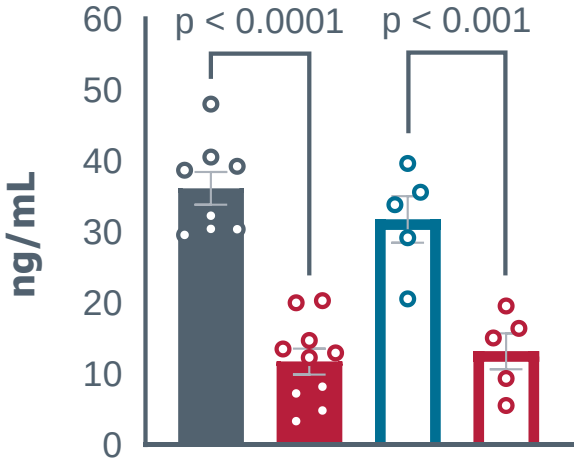
B) Lean Mass



C) Fat Mass



D) Plasma Leptin

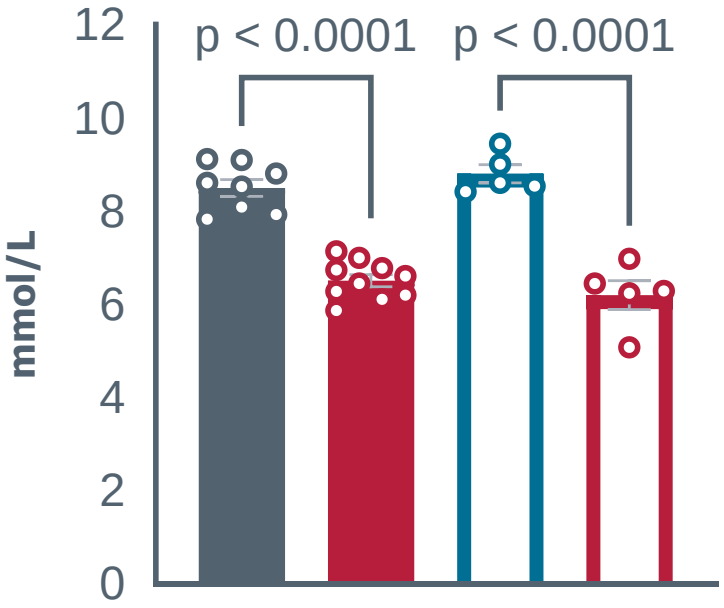


Mean ± SEM shown; n=5-10 per group, 8 weeks post-treatment. BW=body weight, GLP-1RA=glucagon-like peptide 1 receptor agonist, PGTx=pancreatic gene therapy, Sema=semaglutide, VG=vector genomes

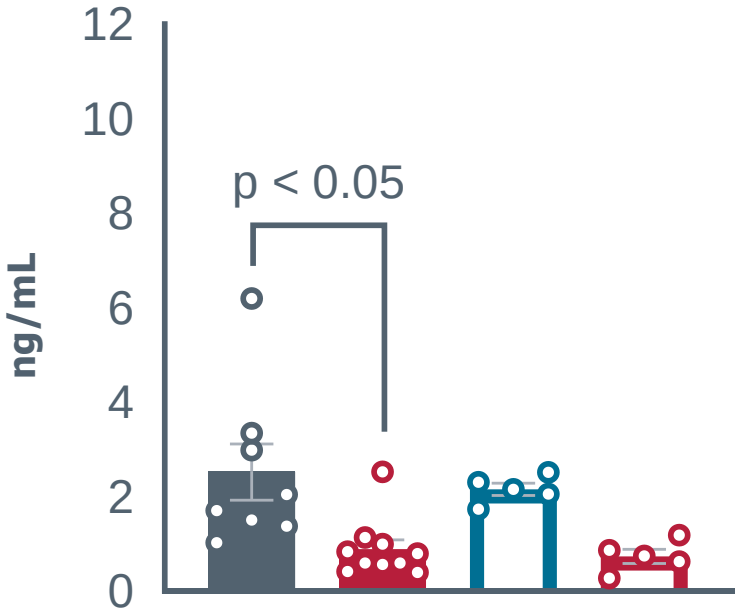
Fasting blood glucose and insulin changes in DIO murine model

Single-dose GLP-1RA PGTx improves FPG and insulin at 8 weeks

A) Fasting Plasma Glucose



B) Fasting Plasma Insulin



AAV Vehicle Control | GLP-1RA PGTx (1e13 VG) | Sema Withdrawal + Vehicle | Sema Withdrawal + GLP-1RA PGTx (5e12 VG)

Mean ± SEM shown; n=5-10 per group. AAV=adeno-associated virus, DIO=diet-induced obesity, FPG=fasting plasma glucose, GLP-1RA=glucagon-like peptide 1 receptor agonist, PGTx=pancreatic gene therapy, Sema=semaglutide, VG=vector genomes

Rejuva development platform

Looking ahead

RJVA-001 T2D Candidate – Native human GLP-1 derived transgene with modified insulin promotor. First-in-human planned for H1 2025 in participants who tolerate GLP-1 drugs

RJVA-002 Obesity Candidate – H2 2024 nomination planned

DIO=diet-induced obesity, FIH=first-in-human, GLP-1RA=glucagon-like peptide 1 receptor agonist, PGTx=pancreatic gene therapy, T2D=type 2 diabetes

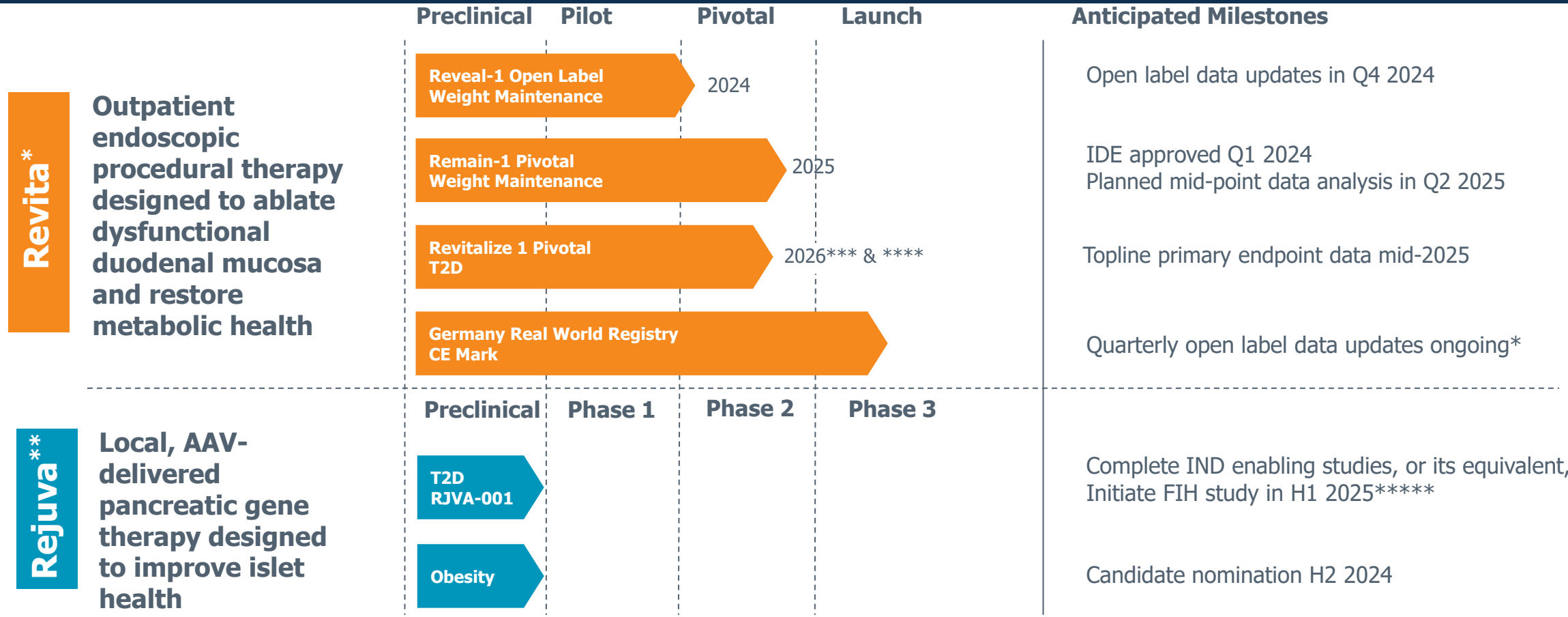
Upcoming Milestones

Harith Rajagopalan, MD, PhD

Co-Founder and Chief Executive Officer, Fractyl

Well-funded with recent IPO proceeds of $110M

Financed to support operations through multiple near-term milestones



*Revita has been granted Breakthrough Device designation for the hydrothermal ablation of the duodenal mucosa to improve glycemic control and eliminate insulin needs in T2D patients inadequately controlled on long-acting insulin; and CE mark obtained from EU and UK in 2016 for Revita for the improvement of glycemic control in patients with inadequately controlled T2D despite oral and/or injectable glucose lowering medications and/or long-acting insulin; **Product candidates under our Rejuva gene therapy platform will undergo Phase 1, Phase 2 and Phase 3 clinical trials ***The Revitalize-1 study is a pivotal study in patients with inadequately controlled T2D on any glucose lowering agent; ****If PMA approved *****subject to IND approval

IND = Investigational New Drug Application with FDA or comparable regulatory body; IDE = Investigational Device Exemption with FDA or comparable regulatory body; FIH = first-in-human; PMA = Premarket Approval

Questions?