Pioneering Prescription Digital Therapeutics for Cardiometabolic Diseases

MAY 2022

Better+
THERAPEUTICS

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Chief Strategy & Commercial Officer

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SEPHORA Yale University School of Medicine UCSF Johnson & Johnson

Better Therapeutics is a prescription digital therapeutics (PDT) company founded on the hypothesis that we can create software to **treat cardiometabolic diseases by changing the patient behaviors that are root causes.**

Next Generation Therapeutics:
Using Software Instead of Drugs

A Digital Therapeutics Platform – delivering novel cognitive behavioral therapy targeting the root causes of cardiometabolic diseases

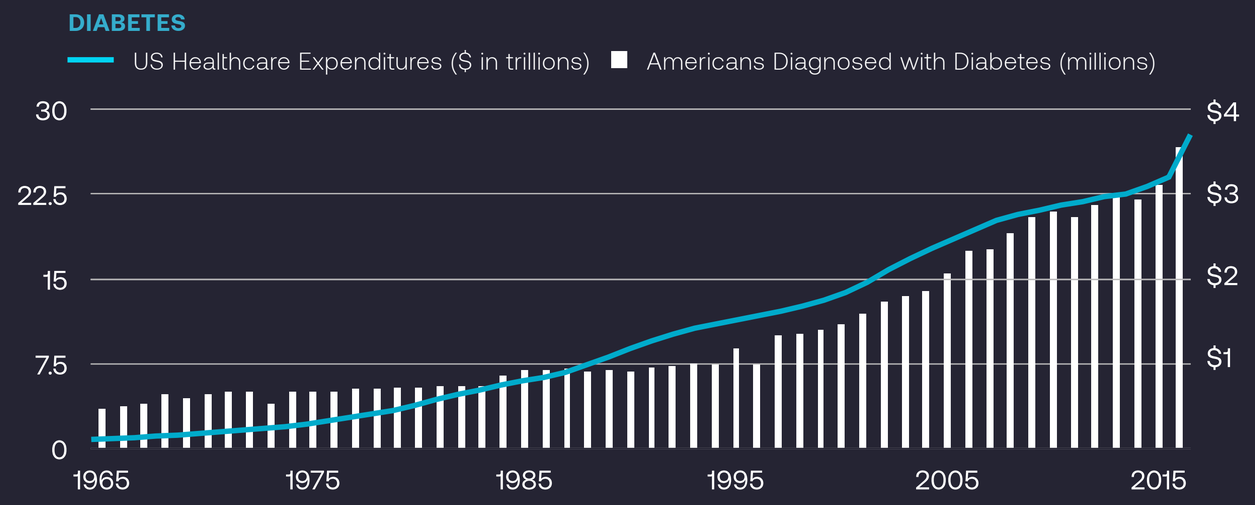
Demonstrated Results– clinically meaningful results in multiple trials for Type 2 Diabetes and Hypertension; completion of randomized, controlled pivotal trial expected in Q2 2022

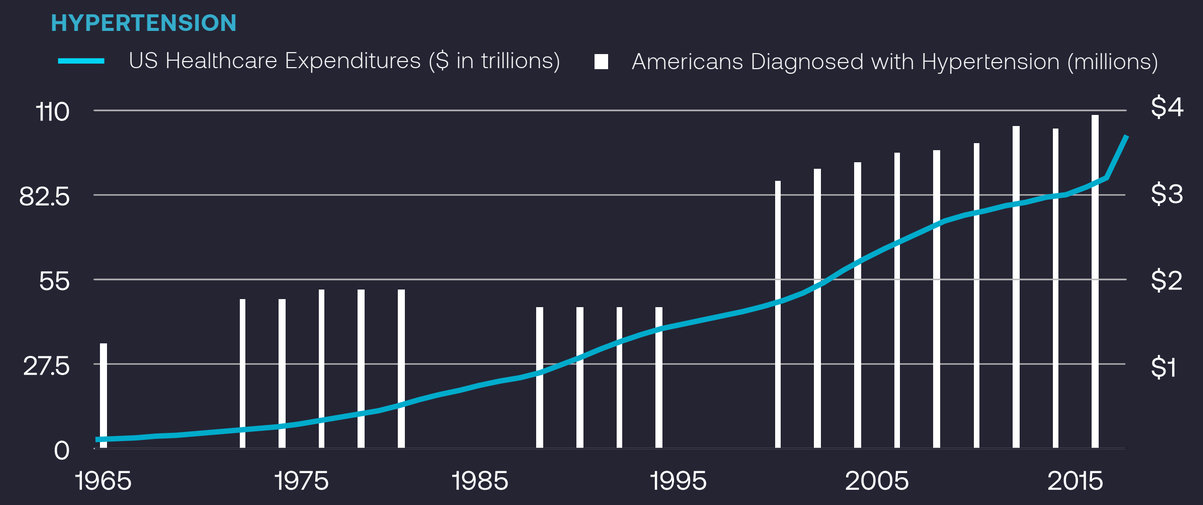
Major Market Opportunities – $490 billion[1] spent in treating the effects of cardiometabolic diseases each year, while leaving the causes in place

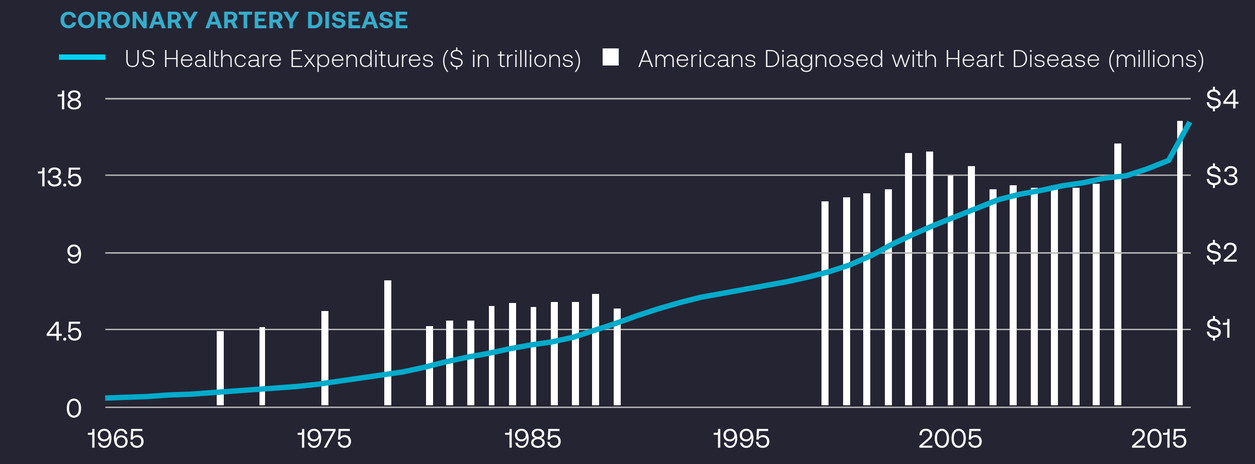
Platform Leverage – because we treat common root causes, we believe we can rapidly iterate our software and efficiently advance our pipeline with minimal product changes

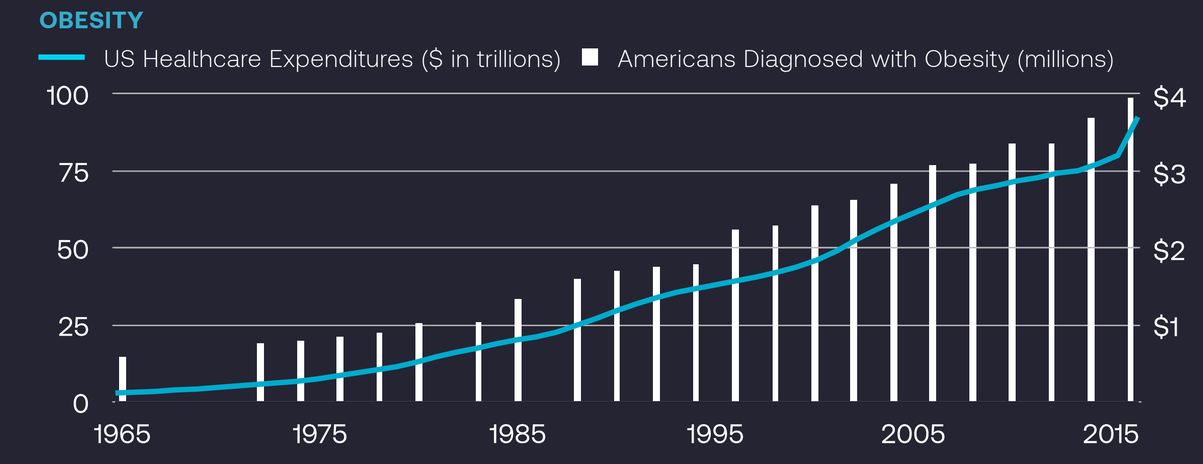
1. Milken Institute. 2017.

We are spending more and more money to get worse and worse outcomes

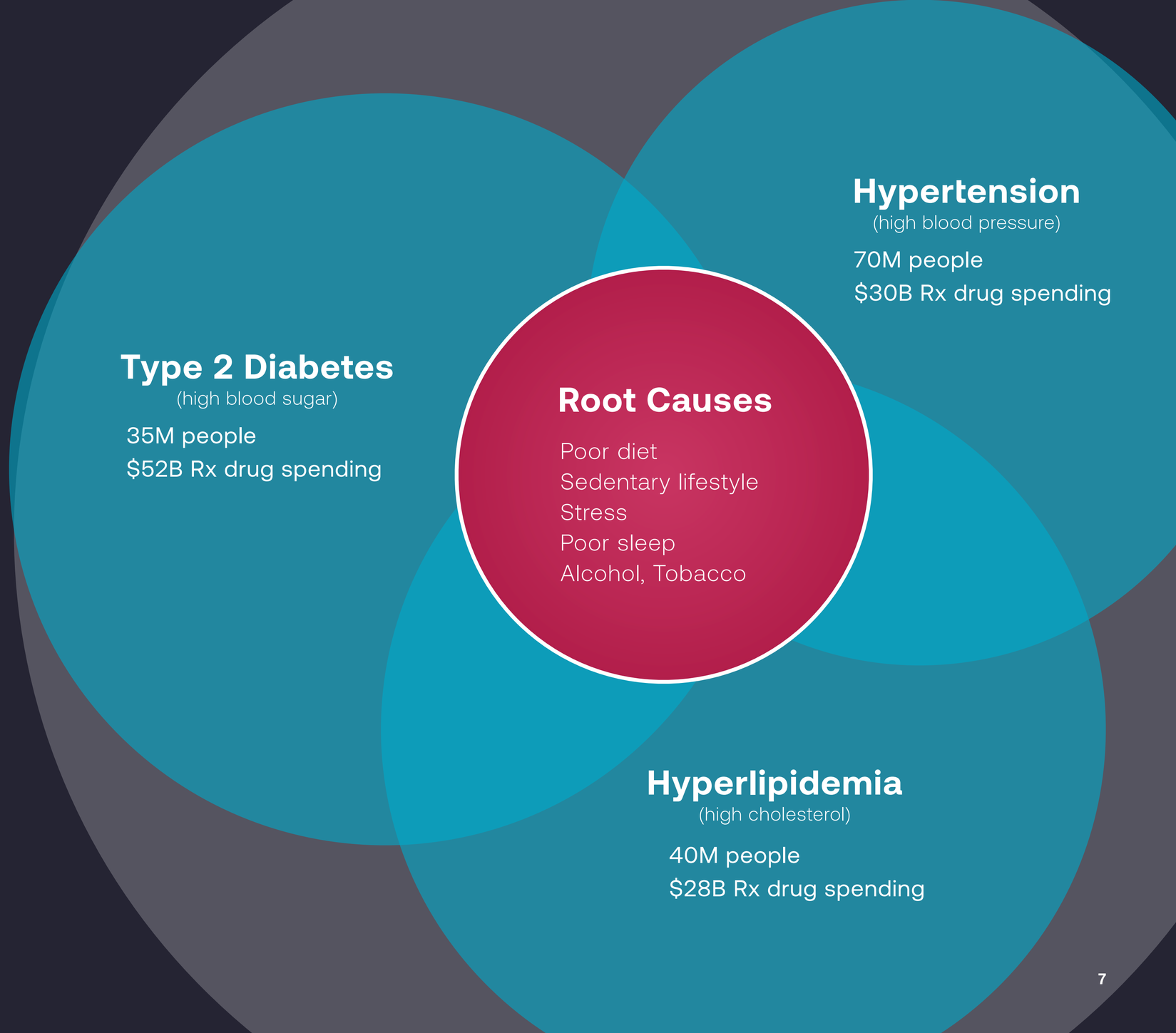








That's because existing therapeutics treat symptoms but leave the common root causes untouched



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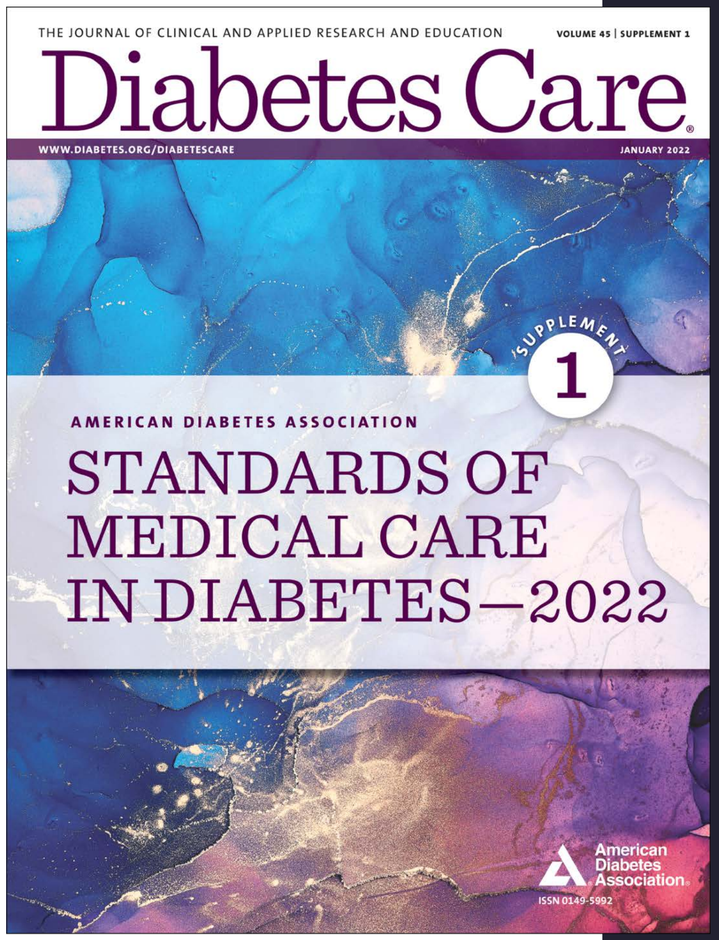


Current clinical guidelines highlight the importance of behavior change as the foundation of treatment, but physicians have no prescribable options

- ✓ Standard of Care guidelines emphasize the importance of behavior change in the management of disease
- ✓ Guidelines call for digital solutions to facilitate behavior change
- ✓ Reimbursement for solutions for behavior change is also encouraged in the latest guidelines
- ✗ However, there are no digital solutions available to be prescribed by physicians to help patients change the behaviors that cause diabetes and other cardiometabolic diseases

Traditional Cognitive Behavioral Therapy (CBT) is effective at addressing the behavioral root causes of cardiometabolic diseases but is neither scalable nor affordable

Not Standardized

Treatment plans to treat cardiometabolic diseases with CBT are not standardized and different health professionals have different levels of success with their patients.

Not Scalable

Patients must commit to 8 - 20 CBT sessions with their healthcare professional.[3]

Not Affordable

Psychotherapists charge upwards of $100/hr and not all patients have insurance that covers treatment.[4]

"The results of this study show that PC-CBT lifestyle intervention [for patients with cardio-metabolic syndrome] leads to remarkable reductions in waist circumference, fasting serum-triglycerides levels, resting systolic blood tension, and improved quality of life when compared to the control group." [1]

"The results of this meta-analysis showed that CBT can be effective in reducing depression symptoms and fasting glucose in diabetes patients with comorbid depression as well as in improving quality of life and anxiety in the long-term." [2]

Sources: 1. Zhang, Y., Mei, S., Yang, R. et al. Effects of lifestyle intervention using patient-centered cognitive behavioral therapy among patients with cardio-metabolic syndrome: a randomized, controlled trial. BMC Cardiovasc Disord 16, 227 (2016) 2. Li C, Xu D, Hu M, Tan Y, Zhang P, Li G, Chen L. A systematic review and meta-analysis of randomized controlled trials of cognitive behavior therapy for patients with diabetes and depression. J Psychosom Res. 2017 Apr;95:44-54. 3. Turner, J. The use of cognitive behavioral therapy in diabetes care: A review and case study. Journal of Diabetes Nursing 14, 3 (2010); Mayo Clinic Cognitive Behavioral Therapy primer 4. Anxiety and Depression Association of America

We created nutritional CBT to treat the root causes of cardiometabolic diseases and can deliver it digitally to make it accessible, affordable and scalable

Targets eating and related behaviors

Given the importance of eating in survival, ideas that shape eating behavior are difficult to change and require direct targeting

nCBT is designed to go far beyond the typical “cognitive distortions” to address a broad but specific set of eating and lifestyle behaviors

Designed for cognitive restructuring

Therapy is delivered via Lessons and Skills that gradually advance, allowing time for cognitive restructuring before moving on to more deeply held beliefs

Includes Lessons and Skills to enhance emotional processing and help uncover the past experiences or cognitive origins of maladaptive beliefs. The intent is to create the emotional resilience and acceptance needed to make enduring changes

Enhances primary care

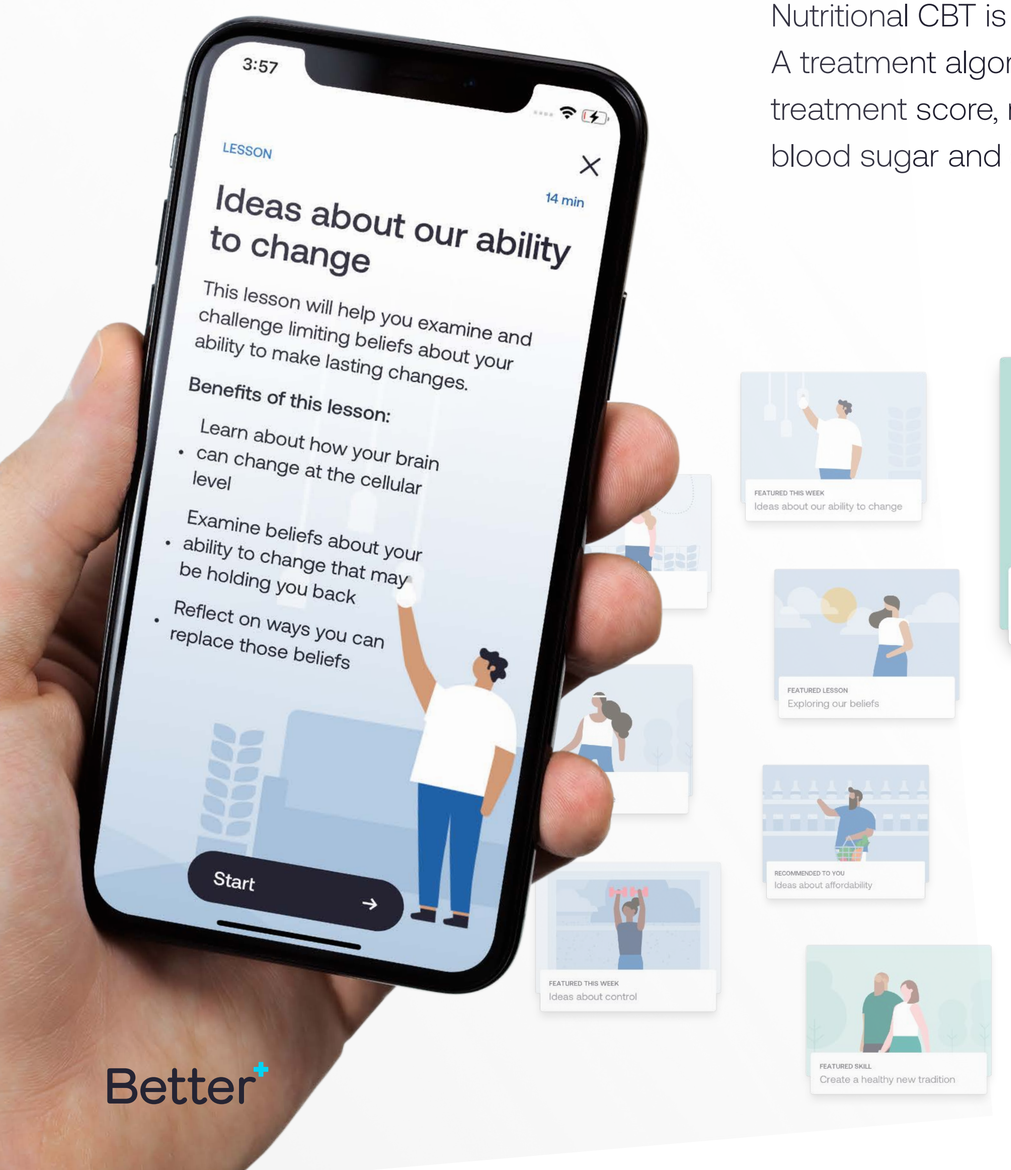
Designed to work within the existing framework of standard medical care and medication use. Lifts the burden of behavior change off of Physician’s plate

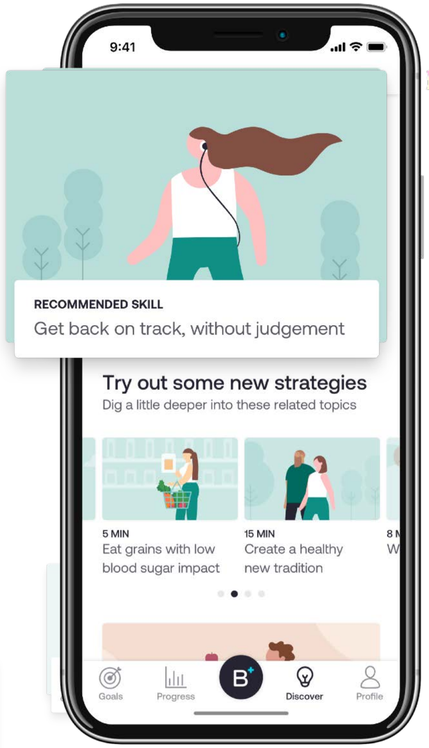
Unifies 3 distinct modalities — behavioral therapy, lifestyle medicine, AI into a single therapeutic experience

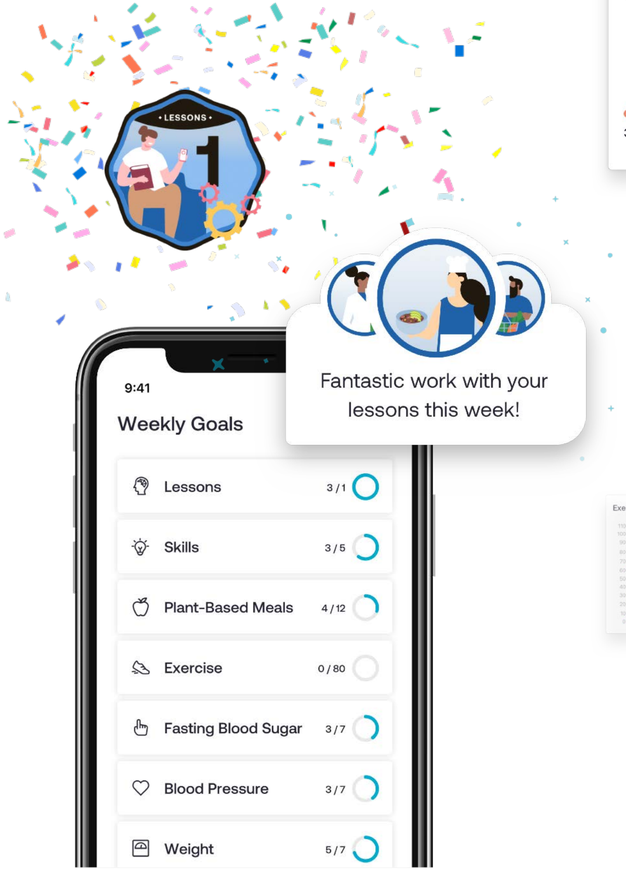
Can be applied to the broad set of cardiometabolic conditions and diverse patient panels typical of Primary Care

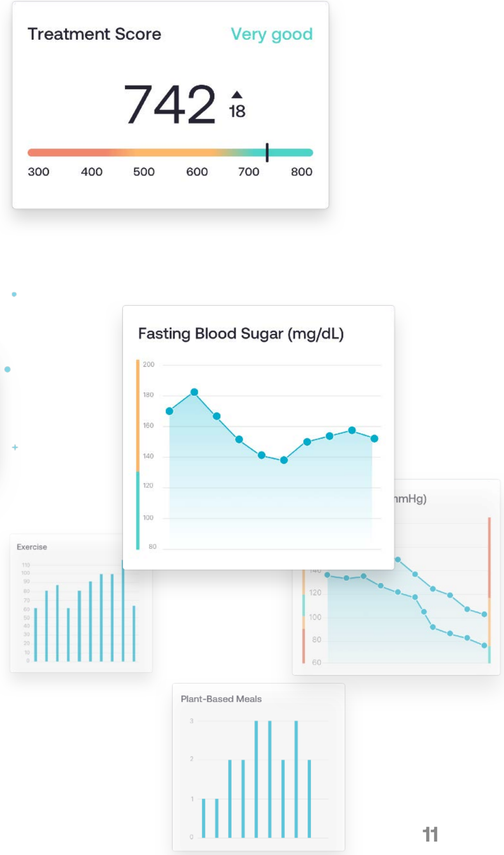
We deliver nutritional CBT using a mobile app prescribed by a physician

Nutritional CBT is delivered via **weekly therapy lessons, skill-building modules, and goal-setting.** A treatment algorithm tailors treatment to each individual patient. Feedback is provided using a treatment score, rewards, and progress reports - to connect changes in behavior to improvements in blood sugar and other biometrics









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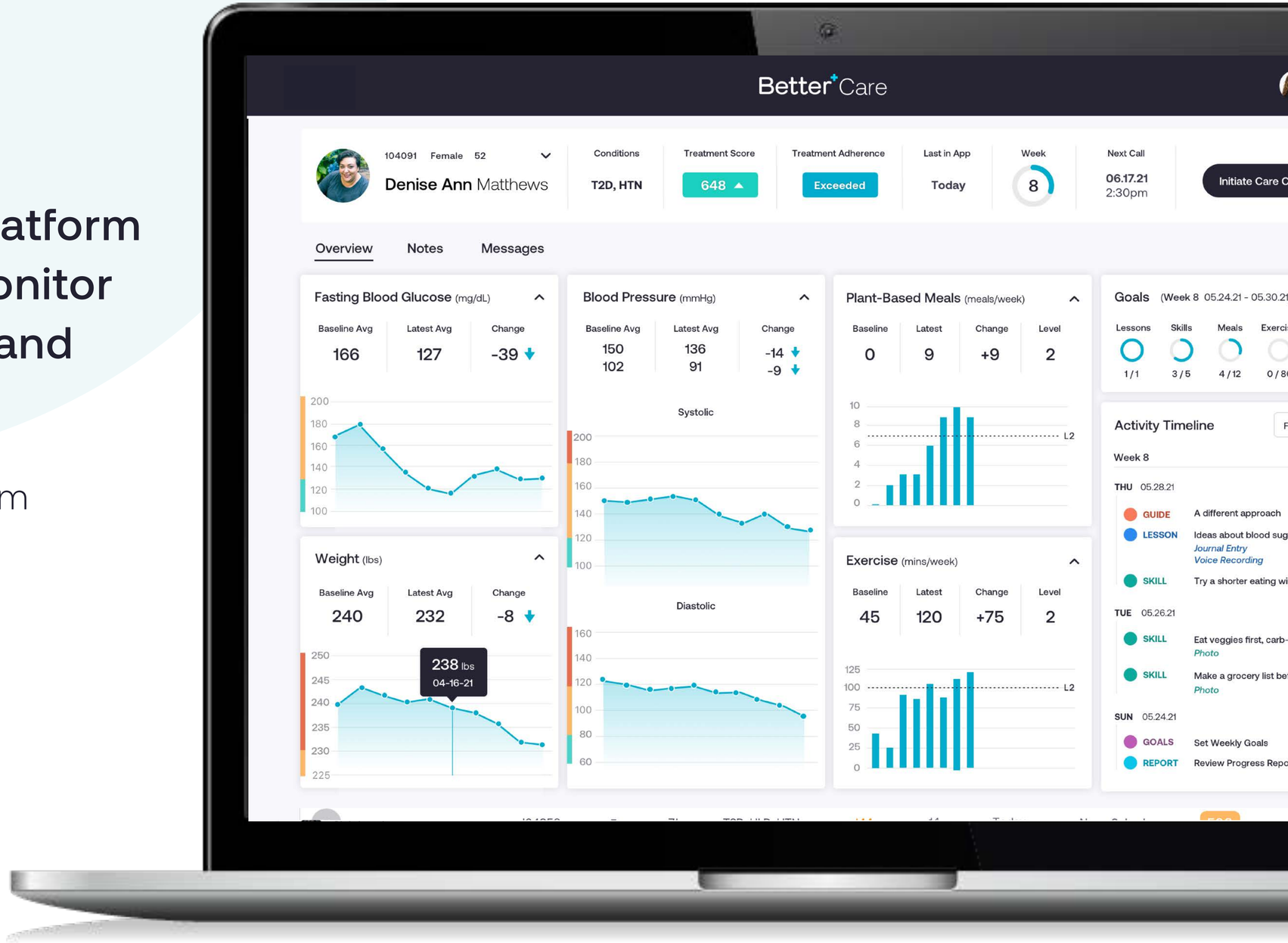
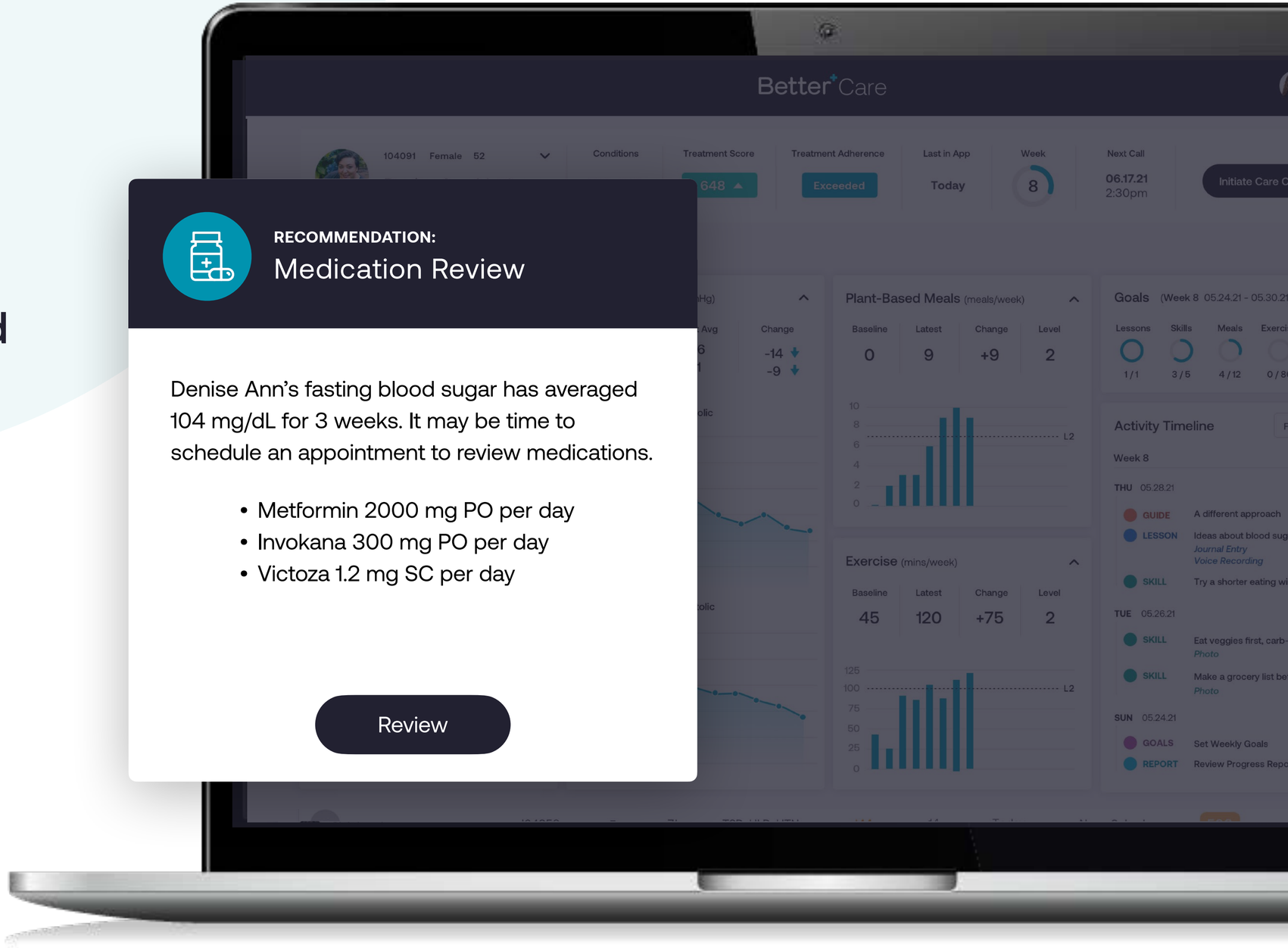
BetterCare is a software platform that allows providers to monitor patients during treatment and intervene when necessary

- Visualize treatment progress from prescription to refill
- Monitor activity and biometrics
- Identify patients at risk
- Enable early intervention



By using patient generated data, providers can make more informed clinical decisions and intervene early when needed



We are advancing a pipeline of PDT products using nCBT to treat multiple cardiometabolic diseases

Additional Scientific Areas of Interest

Increasingly, it is appreciated that there are shared pathways of pathophysiology, such as inflammation and immune activation that underlie the development of cardiometabolic conditions as well as conditions in other disease classes, such as Alzheimer's disease, multiple sclerosis and certain cancers.

- Chronic Kidney Disease
- Pre-Eclampsia
- Coronary Artery Disease
- Treatment-resistant Hypertension
- Familial Hypercholesterolemia
- Alzheimer's Disease
- Gestational Diabetes
- Peripheral Artery Disease

First in class, pivotal RCT demonstrating efficacy in type 2 diabetes

Half of BT-001 participants have clinically meaningful A1c reduction (mean 1.1%)

Clear dose-response signal observed

Favorable benefit to risk ratio...

...in diverse, nationally representative patient population with unmet medical needs

Primary Endpoint (Day 90)

BT-001 arm (n=296) improves A1c by 0.4% vs. Standard of Care Control (n=312) in Intent-to-treat (ITT) Analysis, p = 0.00003

45% of BT-001 participants have clinically meaningful response (A1c improves by ≥ 0.4%) vs. 27% of Control, p<0.00001

Average A1c reduction in responders is 1.1%

No adverse safety signal observed in BT-001

Secondary Endpoint (Day 180)

Changes in A1c between BT-001 and Control group

Changes in medications

Safety measures

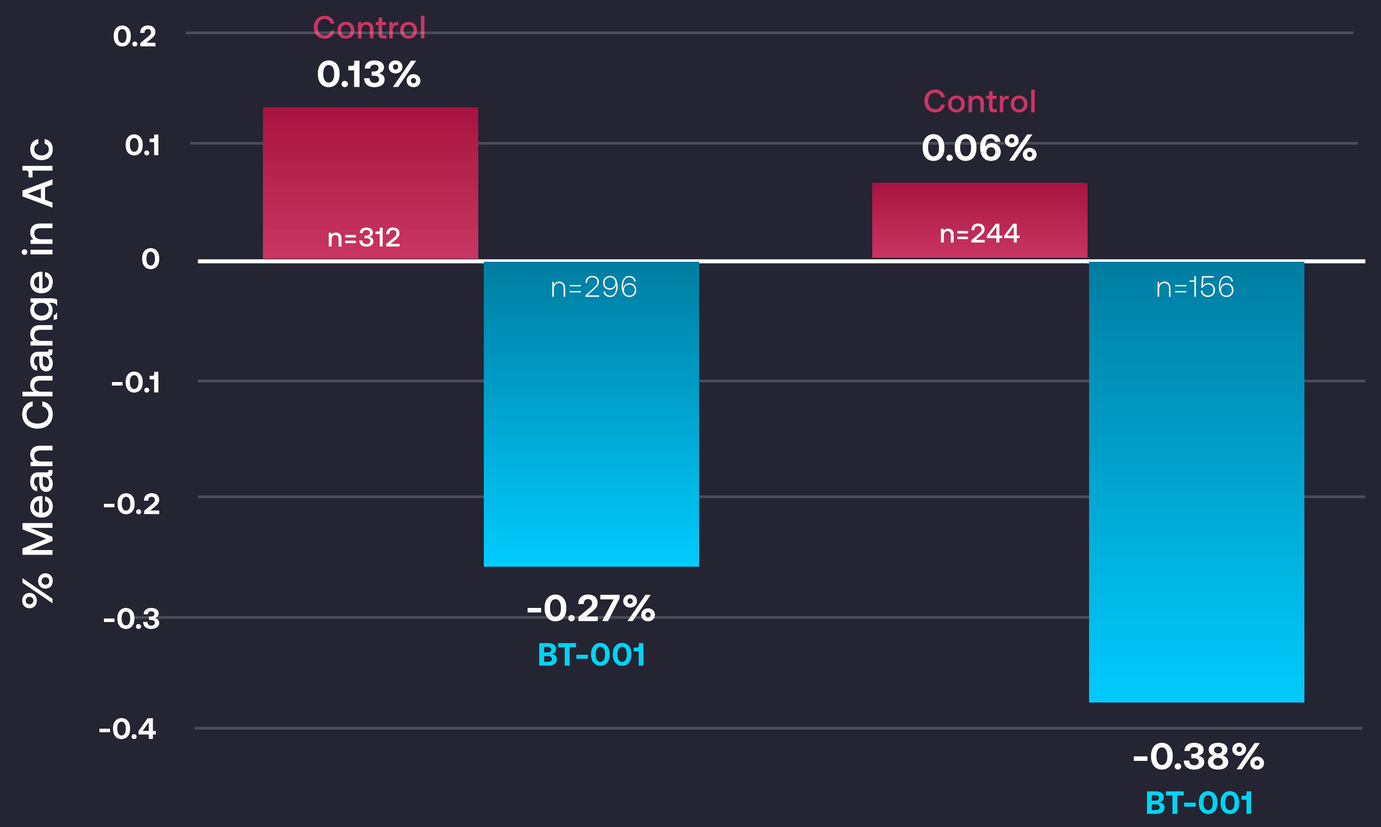
Subgroup analysis

BT-001 n=365 | Control n=360 | 669 Randomized & Onboarded
Powered at 90% to detect
clinically meaningful A1c change (0.4%)

Primary endpoint data at 90 days demonstrated clinically meaningful response with no serious adverse events

Glycemic improvements highly statistically significant. Important study context: COVID, seasonal impact, inconsistent timing of A1c draws.

Trial population represented **racial, ethnic, geographic and socioeconomic diversity**. Participants had long-standing type 2 diabetes, high cardiovascular risk, high degree of co-morbidities and medication use.



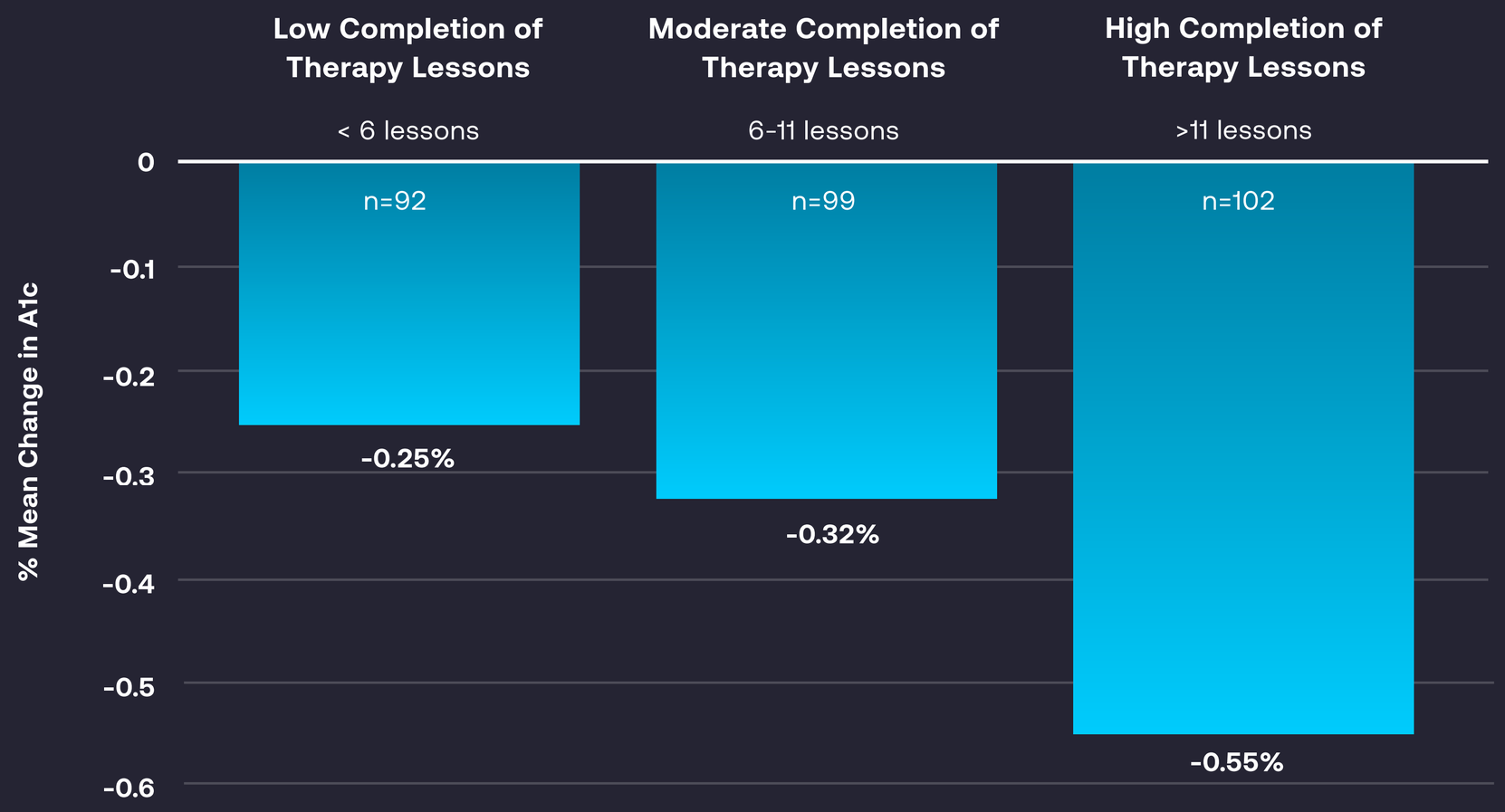
Intent to Treat Population

Δ = 0.4% p = 0.00003

Per Protocol Population

Δ = 0.4% p = 0.0002

Greater engagement in nCBT linked to greater improvement in A1c, indicating a clear dose-response



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During the first 90 days of use, patient engagement and persistence exceed that of consumer health & wellness apps*

*Apptentive | 2022 Mobile Customer Engagement Benchmark Report

6.8 Average **minutes / day** spent in app

8.3 Average number of **Lessons completed** (out of a possible 13)

94% **90 day retention** compared to 36% for consumer healthcare apps*

Healthcare (all)	Medical	Fitness	Health Insurance
36%	38%	36%	35%

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Potential claims based on primary endpoint and anticipated secondary endpoint data

Indications for Use

BT-001 is a prescription-only software program intended to help adult patients with type 2 diabetes improve glycemic control. The software delivers behavioral therapy via a mobile application that targets behaviors related to achieving glycemic control and is intended to reduce A1c.

Clinical Claims

BT-001 is designed to help patients with type 2 diabetes improve glycemic control by lowering A1c

Patients using BT-001 reduced A1c by an average amount of 0.4% when compared to a standard of care control group

45% reduced A1c by 0.4% or more (mean change 1.1%) compared to 27% in the control group receiving standard of care

Efficacy and safety has been evaluated in a diverse, clinically-complex and nationally-representative adult population with type 2 diabetes

“ ***I’ve got time*** *to change... this won’t impact my life.”*

“ *When my symptoms started – dizziness, blurred vision, getting up to go to the bathroom every hour at night, I went to the doctor and was diagnosed.* ***I’m shocked!*** *How did I get here?”*

“ *I’m exhausted. I can’t sleep or seem to think straight.* ***I’m feeling worse*** *and now my vision is deteriorating. They tell me I have nerve and bone damage in my left foot. I’ve been taking 2 medications and now I have to take 3.”*

“ *My doctor is talking about insulin...****I’m scared****. I feel like once you hit insulin you are on a downward slide to the end. There must be something else I can do.”*

A BETTER START

A BETTER STEP UP

Pre-Diabetes	Diagnosis	Non-Insulin Treatment	Additional Non-Insulin Treatments	Insulin Treatment	Advanced Comorbidities
Incremental cost per patient per year	$2,000		$10,000	$19,000	
LIFESTYLE CHANGES	**FIRST LINE TREATMENT**	**DUAL THERAPY**	**TRIPLE THERAPY**	**STEP UP TO INSULIN**	
Changes to exercise and diet	Metformin	Metformin + Sulfonylurea	Metformin + GLP-1 + SGLT2	Metformin + GLP-1 + SGLT2 + Insulin	

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Our value story is compelling to payers and we are substantiating it with robust evidence

Disease burden	Type 2 diabetes is among the largest expenses categories for payers (#1 in Medicare and VA; #5 in commercial insurance); patients with T2D cost an additional $11k per year than individuals without diabetes
Unmet need	Less than 50% of patients with T2D are able to achieve glycemic control with existing therapeutics Despite clinical guidelines that highlight behavior change as the foundation for treating T2D, providers currently have nothing to prescribe
Mechanism of Action	Cognitive Behavioral Therapy (CBT) is effective at changing the behaviors that cause T2D but is not scalable, affordable or accessible Nutritional CBT (nCBT) is an adaptation of CBT specifically designed to address the behavioral root causes of diabetes and can be delivered by a prescription digital therapeutic (PDT) If authorized by FDA, BT-001 will be the first and only way providers can prescribe CBT to their diabetes patients and address root causes
Target patient	Patients with uncontrolled T2D patients on a path to step up to insulin
Safety & effectiveness	BT-001 has shown a clinically meaningful benefit compared to standard of care alone in improving glycemic control by lowering A1c, and has shown no serious adverse events
Cost offsets	BT-001 can displace or delay more costly medications and has the potential to reduce hospitalizations and emergency room visits
Healthcare disparities	BT-001 is effective in populations of greatest need, including those that are racially, ethnically and socioeconomically diverse

Real-world evidence from a 1,000 participant randomized, controlled, multi-site study will inform our understanding of durability, impact on costs and medication use

First Patient In	3-Month Data (250 pts)	6-Month Data (750 pts)	9-Month Data (1000 pts)
Oct-21	Q4-22	Q2-23	Q4-23

	BT-001 Participants	Study Size	Duration
Mass General Brigham	500	750	18-month
CPC Clinical Research	250	500	24-month
Catalyst HEALTH NETWORK	250	250	12-month

Population: Participants with type 2 diabetes; A1c between 7.0% and 11.0%, not on prandial insulin

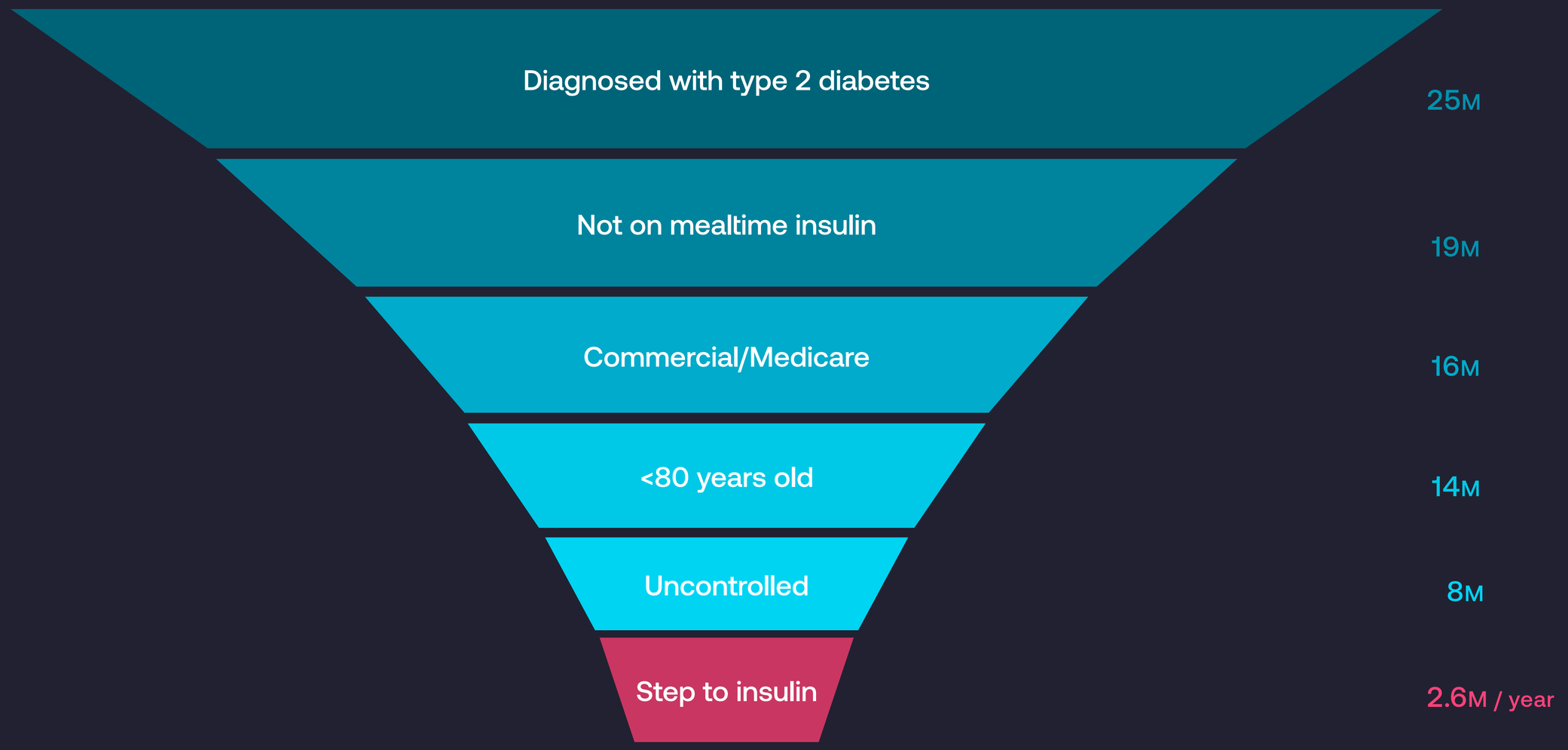
Design: Open-label, real world interventional studies using within participant comparison or control arm

Primary Measures: Mean change in A1c after 6 and 12-months (mean change within participant or compared to control)

Secondary Measures: Mean change in medication usage after 6 and 12-months (mean change within participant or compared to control)

Exploratory Endpoints: Changes in quality of life, diabetes treatment satisfaction, blood pressure, cholesterol, weight, lipids and HbA1c trends, medication use, diabetes related hospitalizations, emergency room visits, and outpatient visits at 12 months or more

If authorized by FDA, we will focus on patients who would otherwise step to insulin or other costly injectables at launch



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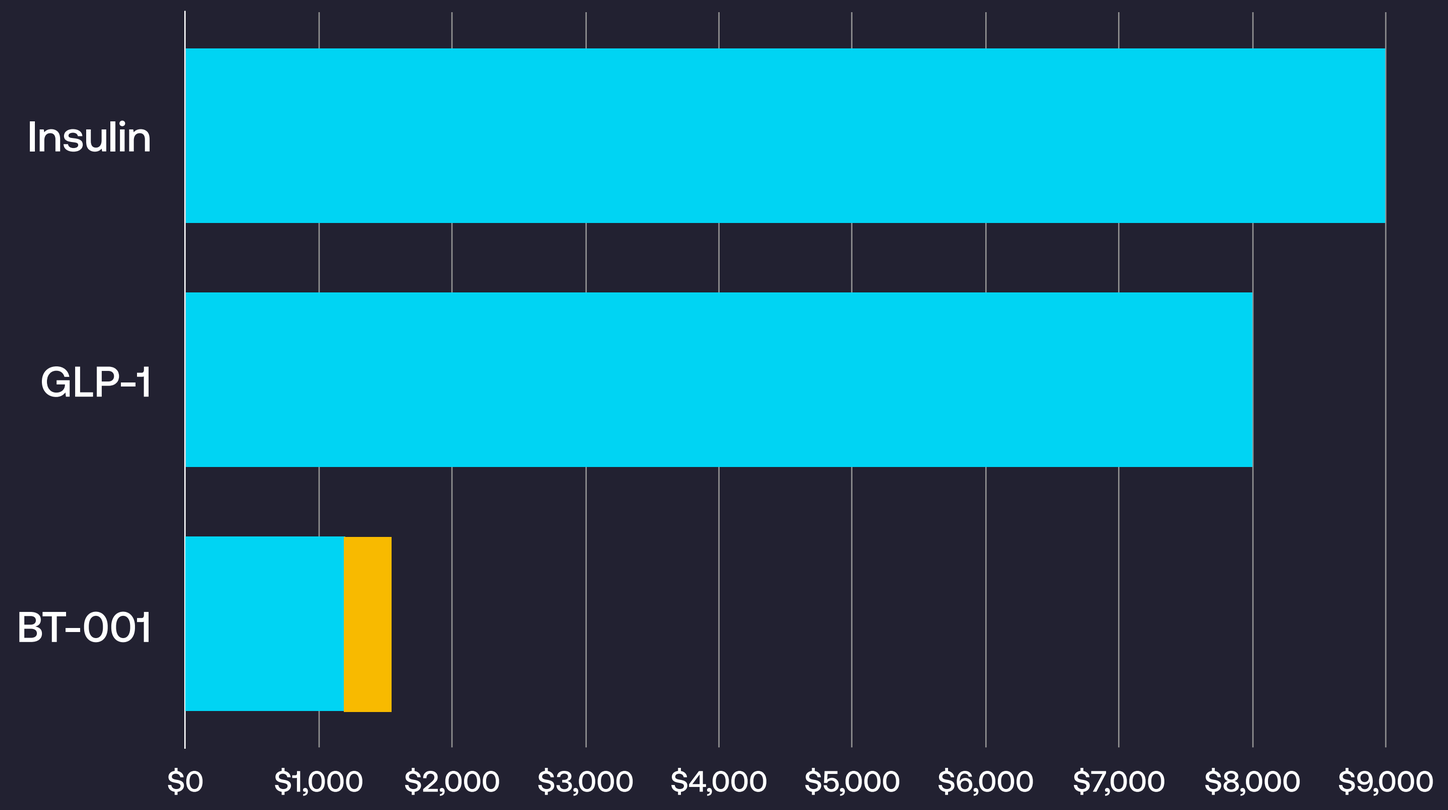
We intend to price in order to provide compelling value to payers and maximize access by minimizing controls such as prior authorizations and step edits

Incremental Healthcare Costs

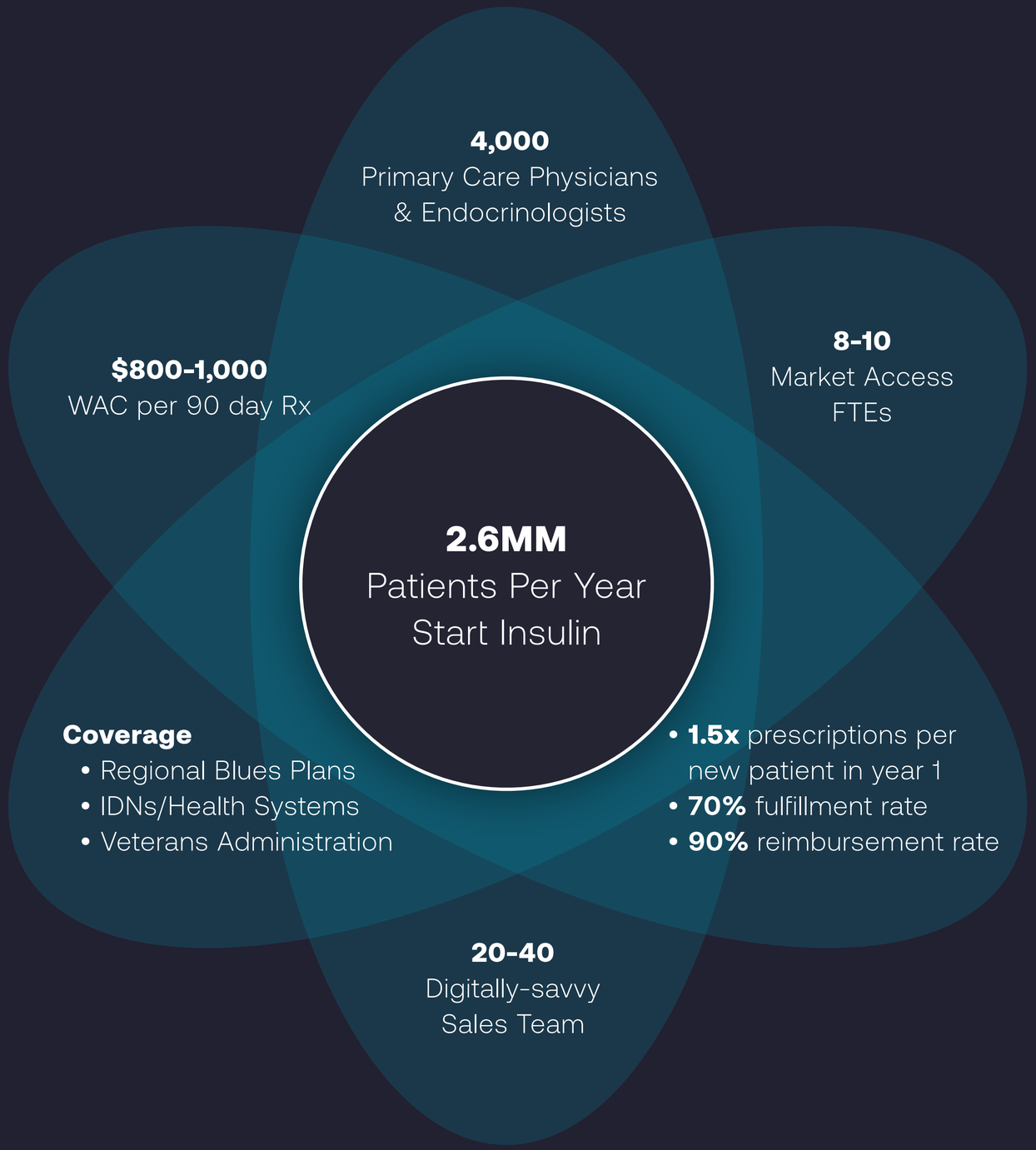
per patient, per year



Source: Symphony claims analysis

At launch, we will focus on securing coverage from regionally dominant, early adopting commercial insurers and health systems.

A team of 20-40 FTEs will engage and educate approximately 4,000 primary care providers and endocrinologists practicing within large health systems and treating a disproportionate number of diabetes patients not well controlled by traditional medications.



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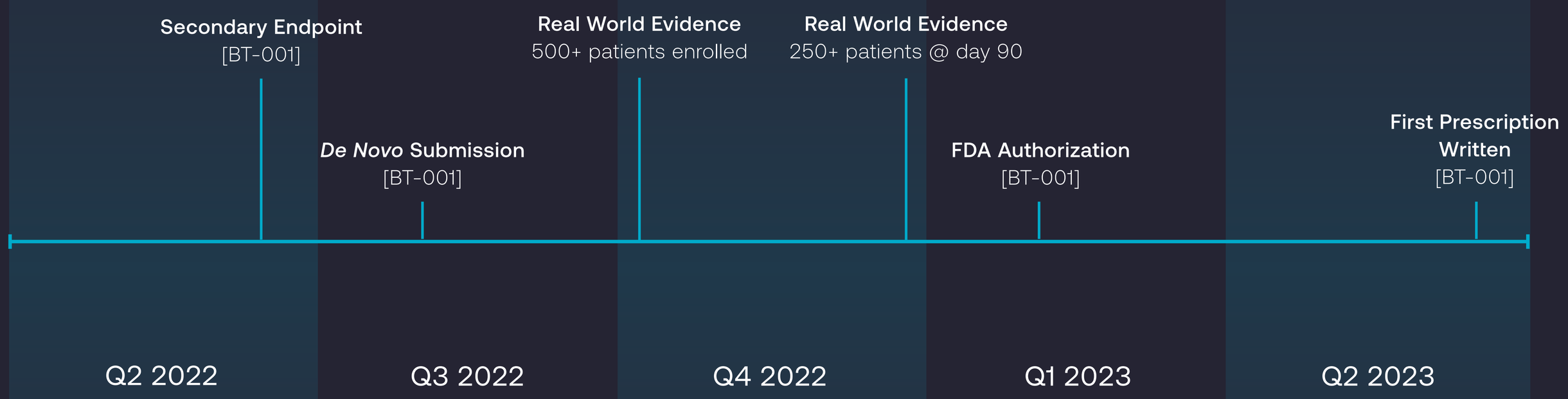
We expect to achieve multiple value creating milestones over the next 18 months



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