



Apps to Fill the Gaps: Optimizing Patient Functioning and Outcomes Using Prescription Digital Therapeutics to Support Pharmacological Treatment in Psychiatric Patients

Supported by an independent educational grant from Boehringer
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Faculty

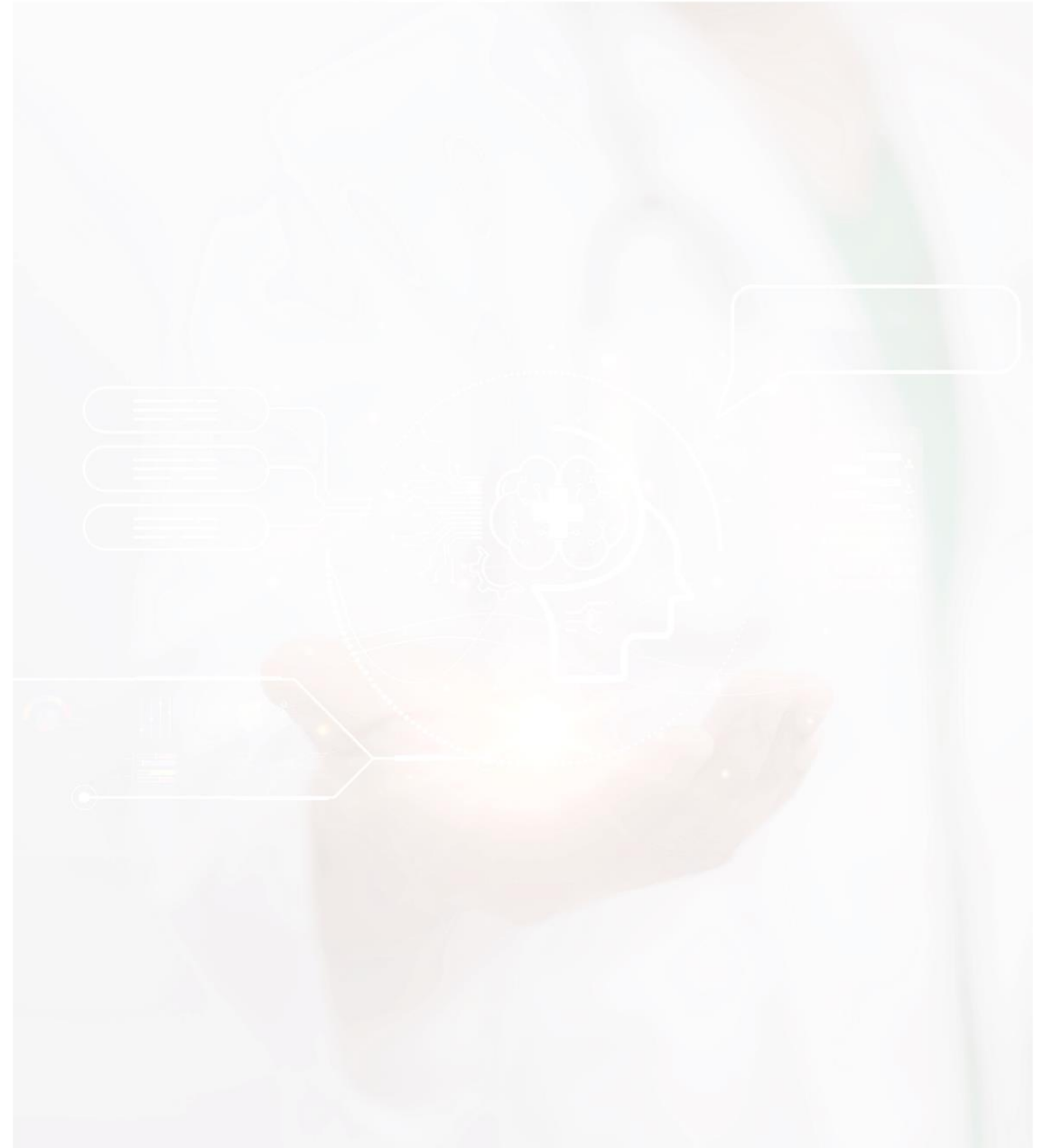
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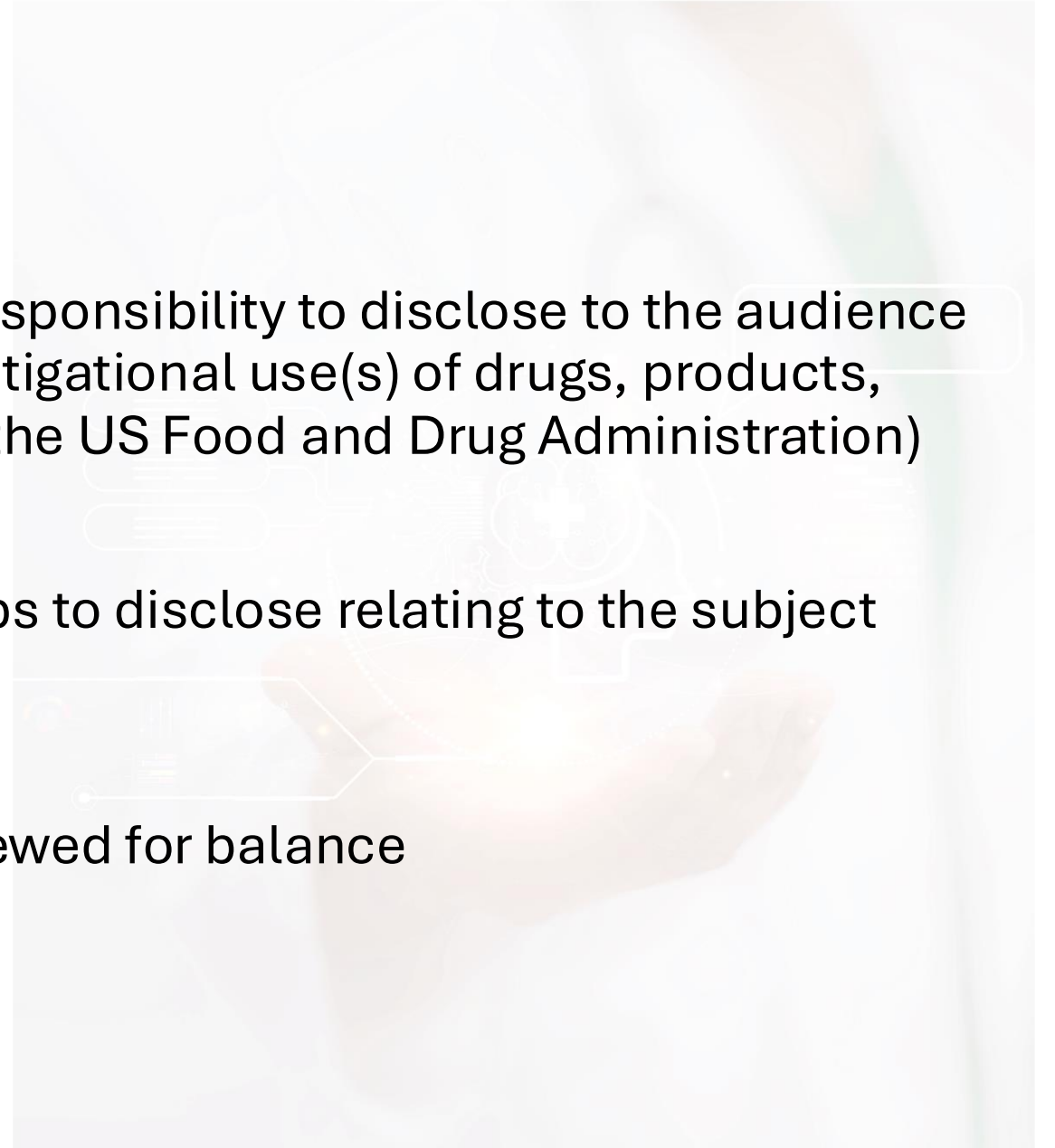
Faculty Disclosures

Andrew J. Cutler, MD

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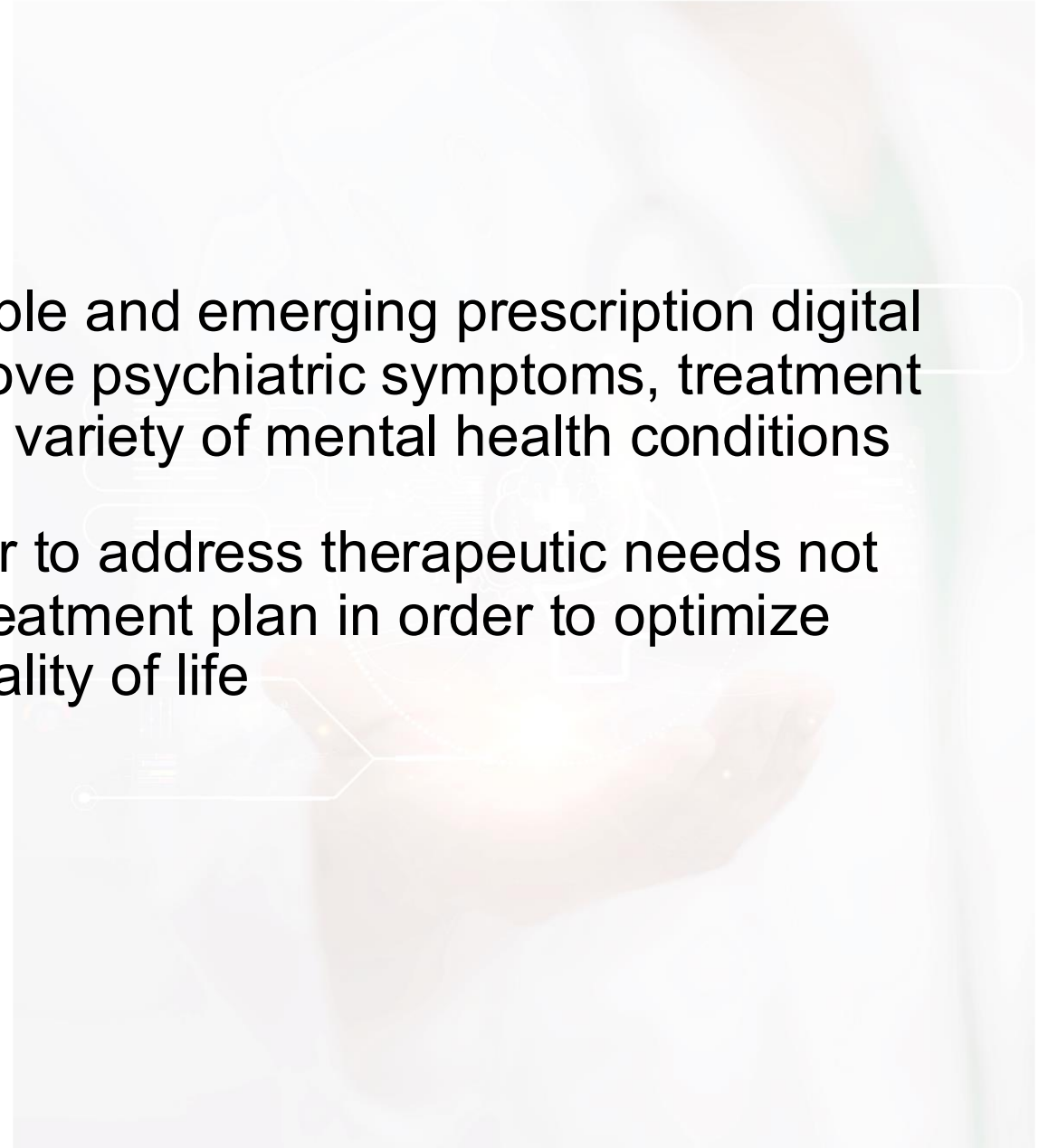
Disclosure

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Learning Objectives

1. Evaluate the evidence base for available and emerging prescription digital therapeutics (PDTs) designed to improve psychiatric symptoms, treatment adherence, and patient outcomes in a variety of mental health conditions
2. Incorporate PDTs into practice in order to address therapeutic needs not adequately mitigated by the current treatment plan in order to optimize patient outcomes, functioning, and quality of life





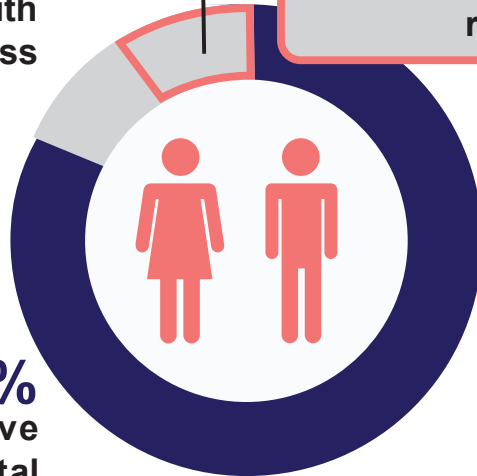
Unmet Needs in Psychiatry Care

Unmet Needs in Psychiatry and Mental Health Care

% of U.S. Adults Who Have Mental Illness and Seek Treatment

20%
Live with mental illness

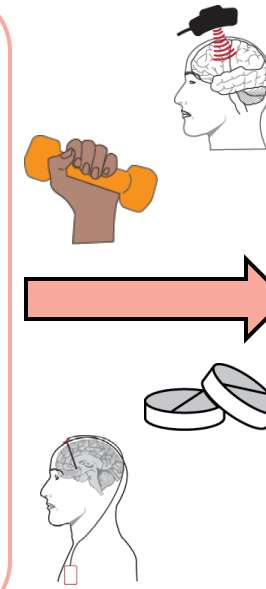
<50%
Of those with mental illness receive any care



80%
Do not have a diagnosed mental health condition

1/5 of U.S. adults live with a mental illness but less than half receive any care

Before Treatment



After Treatment



1/3 of patients with PTSD have clinical-level residual symptoms after treatment

Residual symptoms persist even after treatment, highlighting the need for adjunctive tools

- > 1/3 of adults with **serious mental illness (SMI)**, and 1/2 with any diagnosable mental illness, received no treatment in 2020
- Pandemic spurred teletherapy but **didn't significantly expand access** or new patient engagement in mental health care, especially in racial minorities

Unmet Needs in Mental Health Care May Be Addressed With Digital Therapeutics



Scalable Access

Prescription digital therapeutics (PDTs) have no waitlists or provider shortages, **ideal for rural and underserved communities**



Adherence

Interactive interfaces (CBT, gamified training, neurostimulation) → **higher patient buy-in**



Versatile

PDTs are available for ages 8–65+, offering cross-age solutions



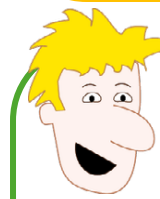
Culturally Conscious

Uniform digital content **minimizes provider bias**, and modules can be **translated/adapted** for diverse populations



Lower Stigma

Subscription models and home use can help **reduce cost barriers and stigma** of clinic visits



Scientifically Sound

PDTs are still regulated by the FDA and are therefore subject to clinical trials and safety metrics

CBT, cognitive behavioral therapy; FDA, Food and Drug Administration

Ridout SJ et al. JMIR Ment Health 2024;11:e56574;

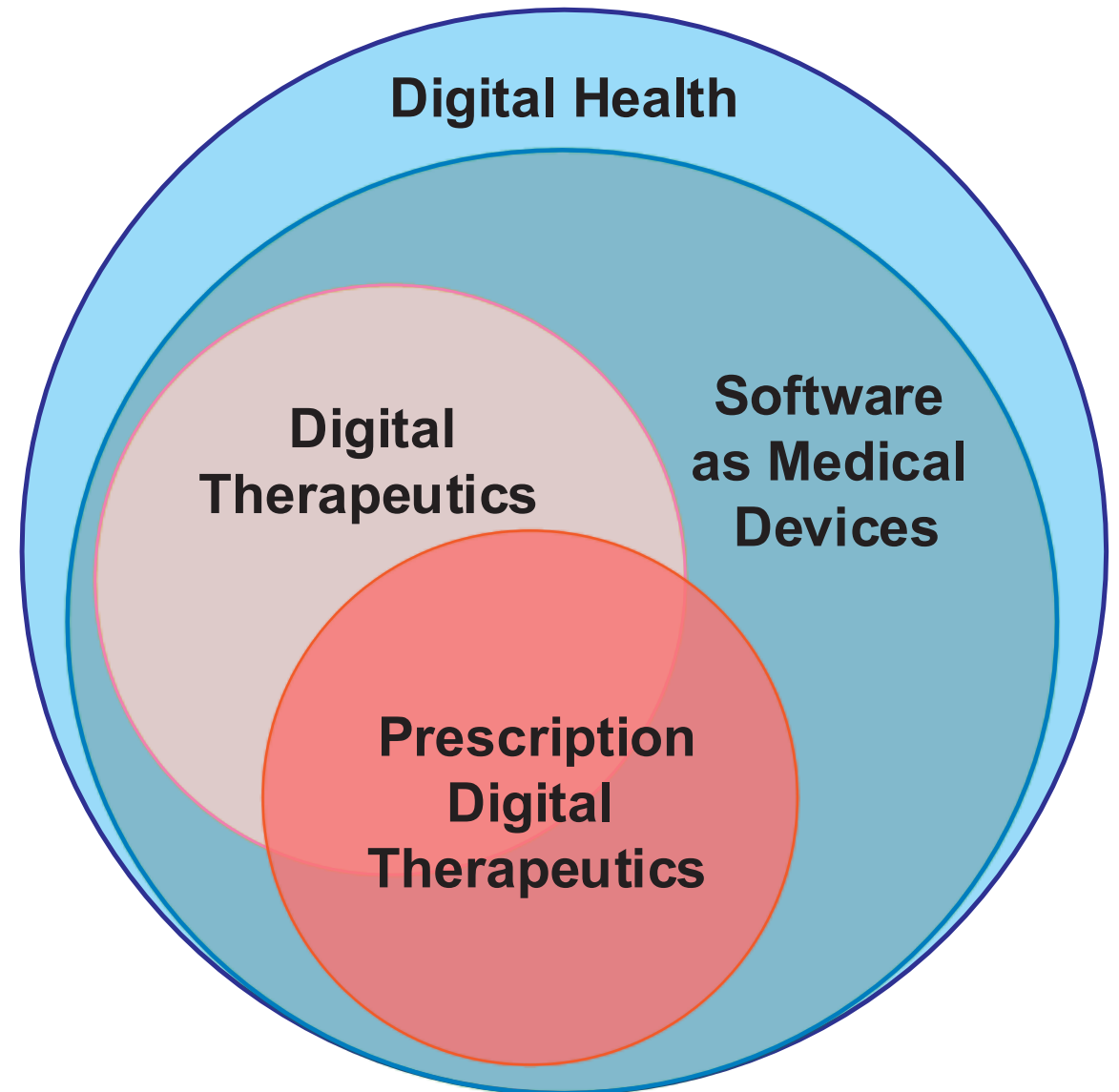
Faria M et al. J Clin Med 2023;12(21):6735; McIntyre RS et al. CNS Spectr 2023;28(6):662-73.



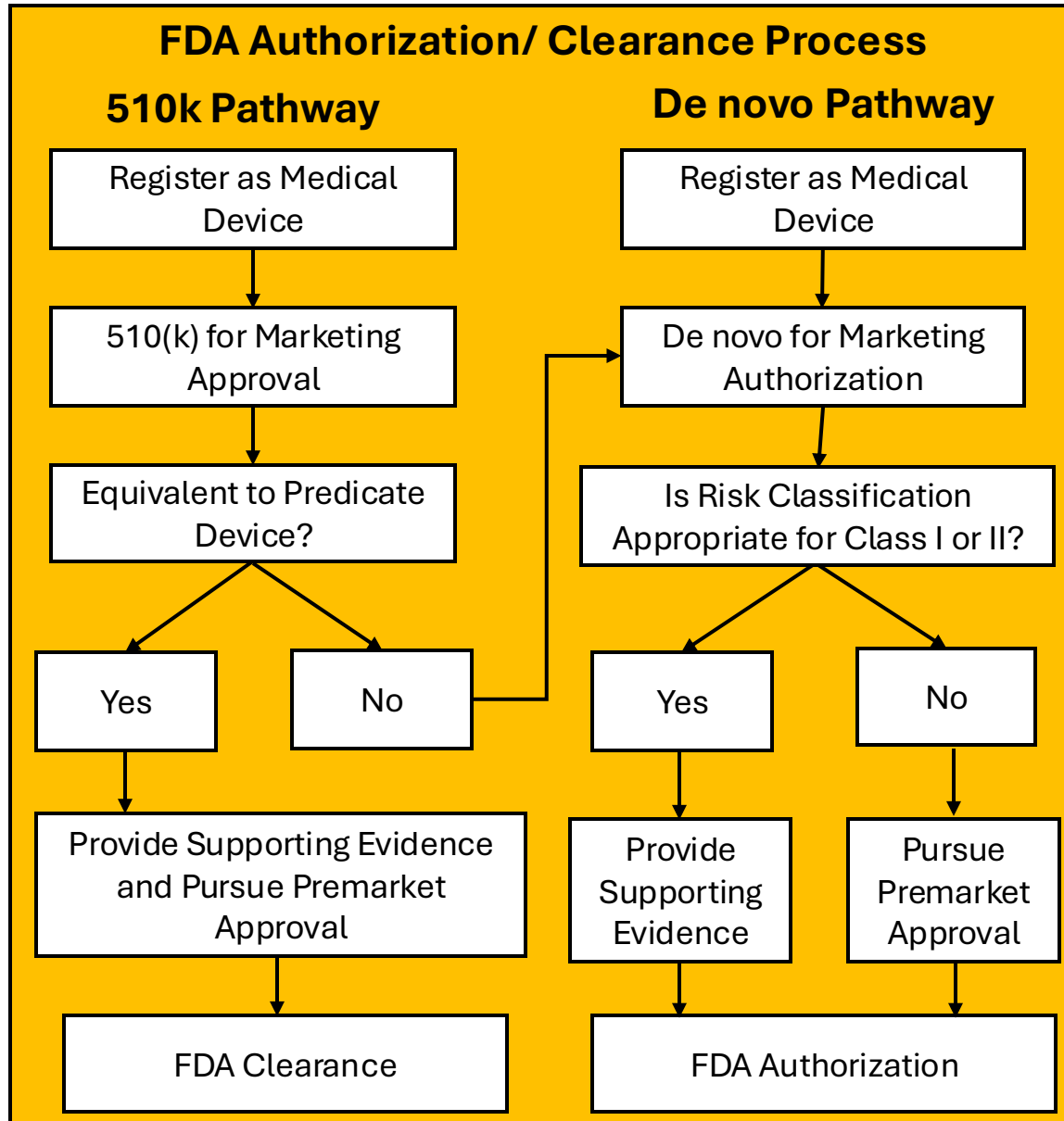
Prescription Digital Therapeutics

What Is a Digital Therapeutic?

- Digital Health: Information, communication technology for health care support
- Software as Medical Devices: Software for medical functions
- Digital Therapeutic: Technology for disease prevention, treatment, or management
- Prescription Digital Therapeutic



FDA Clearance Process for PDTs



- 510(k) is a premarketing submission made to the FDA demonstrating the device is safe and effective
 - Effectiveness is documented by proving substantial equivalence to a legally marketed device (predicate device)
 - If no predicate device exists, the de novo regulatory pathway for low- to moderate-risk devices of a new type can be used
 - Controls and clinical and/or nonclinical data to ensure reasonable assurance of safety and effectiveness
- De novo applications need to document:
 - Probable benefits of the device compared to probable or anticipated risks
 - Controls and clinical and/or nonclinical data to ensure reasonable assurance of safety and effectiveness

When Meds Aren't Enough: Meet Eddie

Hypothetical Case Study

Diagnosis: Schizophrenia

- History: Positive symptoms (hallucinations, delusions) well-controlled on aripiprazole for the last 15 months

Treatment:

- Aripiprazole 15mg daily
- No recent hospitalizations

Eddie continues to struggle with persistent negative symptoms and functional disengagement:

- Apathetic, disengaged socially, has emotional blunting, and other stereotypical negative symptoms
- Negative Symptom Assessment (NSA-16): 52
- Clinical Assessment Interview for Negative Symptoms and Pleasure Scale (CAINS-MAP): 28

Key Takeaways

- Negative symptoms are a driving factor of patient well-being
- We've done everything 'right' with meds, but he's stuck

Patient Case (Eddie, 29-year-old male)



"Not broken, but not okay"



Anhedonia



Emotional blunting



Difficulty engaging socially



Apathy



Sluggish thinking



Positive symptoms *controlled*



Given up hobbies

How a PDT Can Help Eddie Move Forward

Treatment:

- No med changes due to tolerability and effectiveness
- Added in PDT **CT-155**, a smartphone app for **negative symptoms of schizophrenia** that is **currently in Phase 3 trials**

Outcome:

- CAINS-MAP: 28 → 18
- Eddie describes feeling “more awake emotionally”
- Reconnected with friends, restarted art hobby
- Reported more energy and “spark” returning

"I feel like I am finally working my way back emotionally."



Key Takeaways

- Eddie's case highlights the **power of PDTs to address residual symptoms** left behind by meds and therapy
- CT-155 didn't replace pharmacotherapy, **but rather complemented it**, helping unlock emotional and cognitive progress
- **Reflects a broader opportunity** to personalize and enhance treatment plans using digital tools

Available Prescription Digital Therapeutics

PDT	Therapeutic Area	Mechanism of Action
FDA cleared or FDA authorized as of July 2025; available to prescribe		
reSET	Substance Use Disorder	CBT modules with Community Reinforcement Approach, fluency training, contingency management
reSET-O	Opioid Use Disorder	CBT modules with Community Reinforcement Approach, contingency management, buprenorphine check-in
NightWare	PTSD-Associated Nightmares	Sensor-driven device using Apple Watch and iPhone to detect and interrupt nightmares via vibration
PRISM	PTSD	EEG-based biofeedback using amygdala-derived electrical fingerprint
Freespira	Panic Disorder and PTSD	Biofeedback with CO2 and respiration monitoring
DaylightRx	Generalized Anxiety Disorder	CBT-based digital intervention
Modius Stress	Generalized Anxiety Disorder	Neurostimulation via cranial nerve modulation using a wearable headset
MamaLift Plus	Postpartum Depression	Self-guided modules with goal setting, symptom tracking, clinician monitoring
Rejoyn	Major Depressive Disorder	CBT-based lessons, Emotional Faces and Memory Task (EFMT), personalized reminders
SleepioRx	Chronic Insomnia	Digital CBT for Insomnia (CBT-I) in six sessions
Somryst	Chronic Insomnia, Depression	Digital CBT for Insomnia and Depression (CBT-I/CBT-D) with structured therapy modules
EndeavorRx	ADHD	Gamified neurocognitive training delivered through a mobile video game to target attention function
CT-132	Episodic Migraine	Behavioral techniques including CBT to modulate neurocircuitry
RelieVRx	Chronic Lower Back Pain	Virtual reality that includes CBT, pain neuroscience education, diaphragmatic breathing, and mindfulness training
In the Pipeline to be FDA-cleared or FDA-authorized		
CT-155	Schizophrenia	Daily in-app activities, cognitive retraining targeting negative symptoms

Phan P et al. *Bioeng Transl Med* 2023;8(4):e10536; Colbert BM et al. *Front Psychiatry* 2025;15:1550666; Brezing CA, Brixner DI. *Adv Ther* 2022;39(12):5301-6; Lakhan SE. *Cureus* 2025;17(5):e84528.

How Do PDTs Actually Work?

CBT

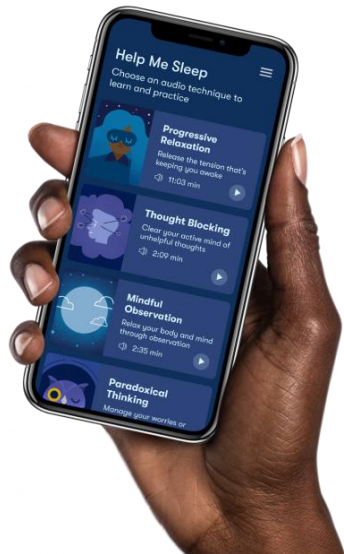
Cognitive Behavioral Therapy Modules

Digitized, structured CBT lessons delivered via app or web, often with interactive exercises or journaling prompts

- Reinforces behavioral activation, cognitive restructuring, sleep hygiene, etc.
- Ideal adjunct when patients can't access a therapist weekly

Examples:

- CT-132 (Migraine)
- Somryst / SleepioRx (Insomnia)
- DaylightRx (Anxiety)



Cognitive Retraining, Gamified Neuroactivation

Interactive tasks that retrain attention, emotion processing, or memory networks; often uses gamification for engagement

- Targets underactive or dysregulated cognitive systems
- Engages brain using neuroplasticity

Examples:

- EndeavorRx (ADHD)
- Rejoyn (MDD) – emotional faces and memory task



Sensor-Driven or Physiological Feedback Loops

Use of wearables, sensors, or app-linked hardware to provide real-time physiological input

- Non-verbal, somatic intervention targeting sleep, arousal, panic

Examples:

- NightWare (PTSD)
- Freespira (PTSD)
- PRISM (PTSD)



Rejoyn for Major Depressive Disorder (CT-152)



Mobile app uses CBT-based lessons with a small amount of gamification

- 3x per week for 4 minutes
- EFMT exercises/games 3x per week for 11–26 minutes
- Personalized reminders and messages regularly for <1 minute for 6 weeks

Intended to:

Decrease depressive symptoms in individuals with MDD aged 22+

Rejoyn user interface



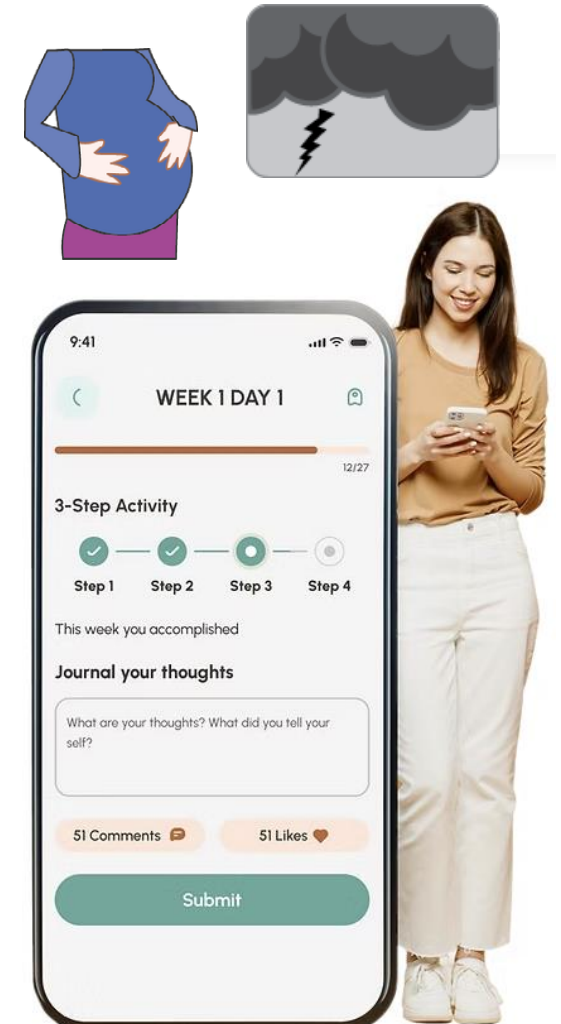
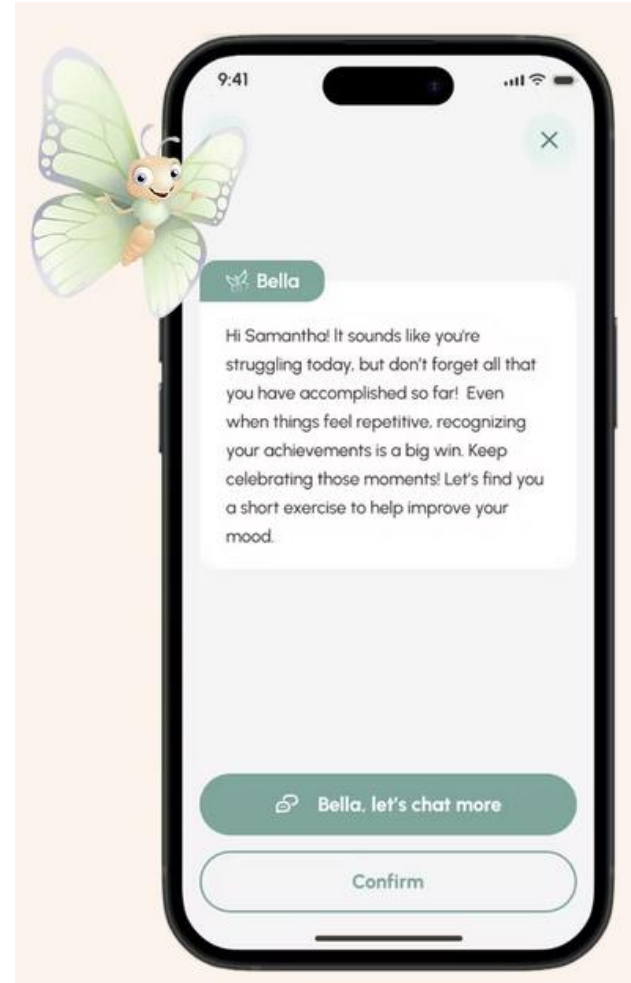
CBT: cognitive behavioral therapy; EFMT: emotional faces and memory task

MamaLift Plus for Postpartum Depression

- First FDA-cleared PDT for postpartum depression
- Eight interactive self-guided modules over the course of 8–9 weeks that includes goal setting, symptom tracking, and monitoring for clinicians
- Led to significant improvement of 4 or more points on the Edinburgh Postnatal Depression Scale (EPDS) in clinical trials
- 83.2% of participants reached an EPDS score of below 13 compared to 32.6% of the sham group

Intended to:

Provide symptomatic relief for those experiencing postpartum depression



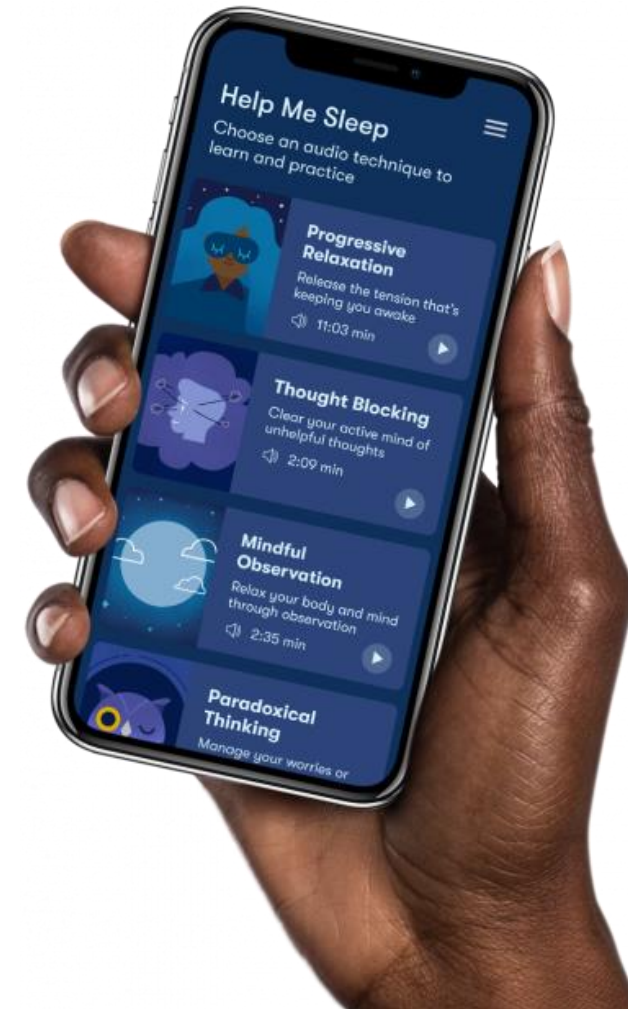
SleepioRx for Insomnia

- Digital cognitive behavioral therapy for insomnia (CBT-I) in six sessions that last about 20 minutes each over the course of up to 24 weeks
- Studied in the context of insomnia with comorbid stroke and/or anxiety
- Large improvements (Cohen's d , -1.46) to sleep-related quality of life measured using the Glasgow Sleep Impact Index

Intended to:

Improve sleep-related quality of life, insomnia, and subjective sleep quality

SleepioRx user interface





reSET for Substance Use Disorder

reSET app user interface

- 61 interactive modules with Community Reinforcement Approach lessons, fluency training, and contingency management through rewards
- Patients ≥ 18 years enrolled in outpatient treatment under the supervision of a clinician who can follow patient-reported substance use, cravings, and triggers for deeper interaction at face-to-face meetings

The first screenshot, titled 'Review Your Progress', shows a line graph of 'CRAVINGS' on the y-axis (0 to 10) against days on the x-axis (1 to 30). Below the graph are tabs for 'DAY', 'WEEK', and 'MONTH'. Underneath is a bubble chart of 'TRIGGERS' with categories: PAIN (purple), ANGRY (orange), OTHER (red), TIRED (blue), HUNGRY (yellow), LONELY (green), and SOCIAL PRESSURE (brown). A text box below the chart states: 'This month, you were triggered mostly by Pain and Other.'

The second screenshot shows the 'reSET' logo and a large green button labeled 'START YOUR THERAPY'. Below this are two smaller buttons: 'Review your progress' and 'Report your status'.

The third screenshot, titled 'Report Your Status', contains the following questions and input fields:

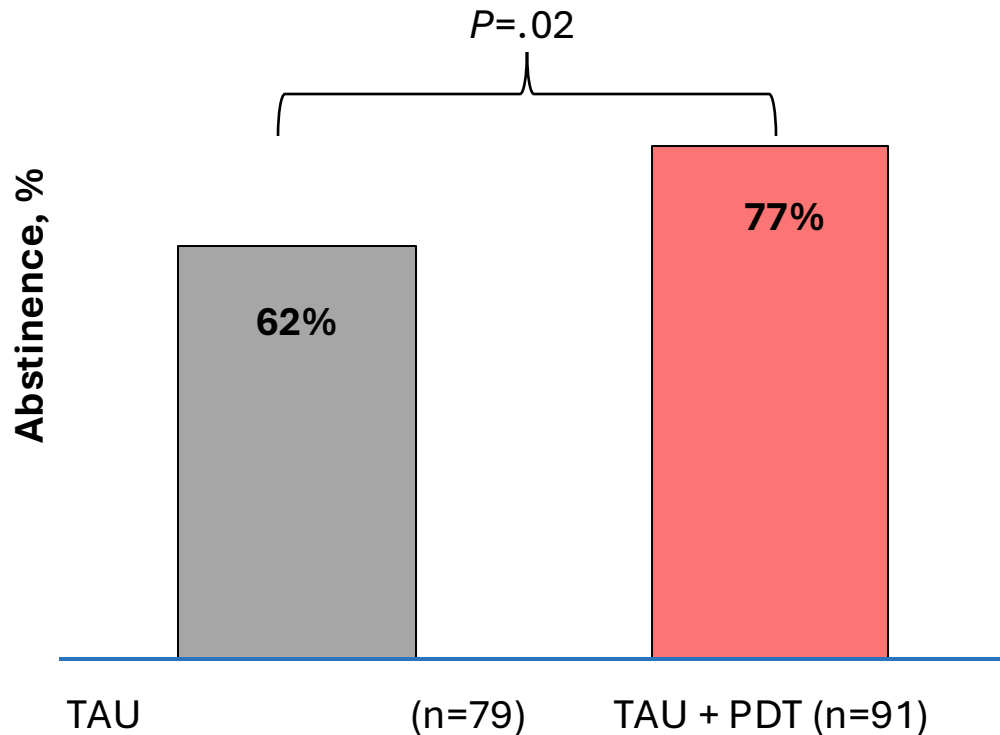
- 'Have you used today?' with radio buttons for 'Yes' (selected) and 'No'.
- 'How strong is your craving right now?' with a slider set to 6.
- 'What triggers are affecting this craving?' with sliders for:
 - HUNGRY: 4
 - ANGRY: 2
 - LONELY: 7
 - TIRED: 0
 - SOCIAL PRESSURE: 3
 - PAIN: 10
 - OTHER: 6

A green 'SUBMIT' button is at the bottom.

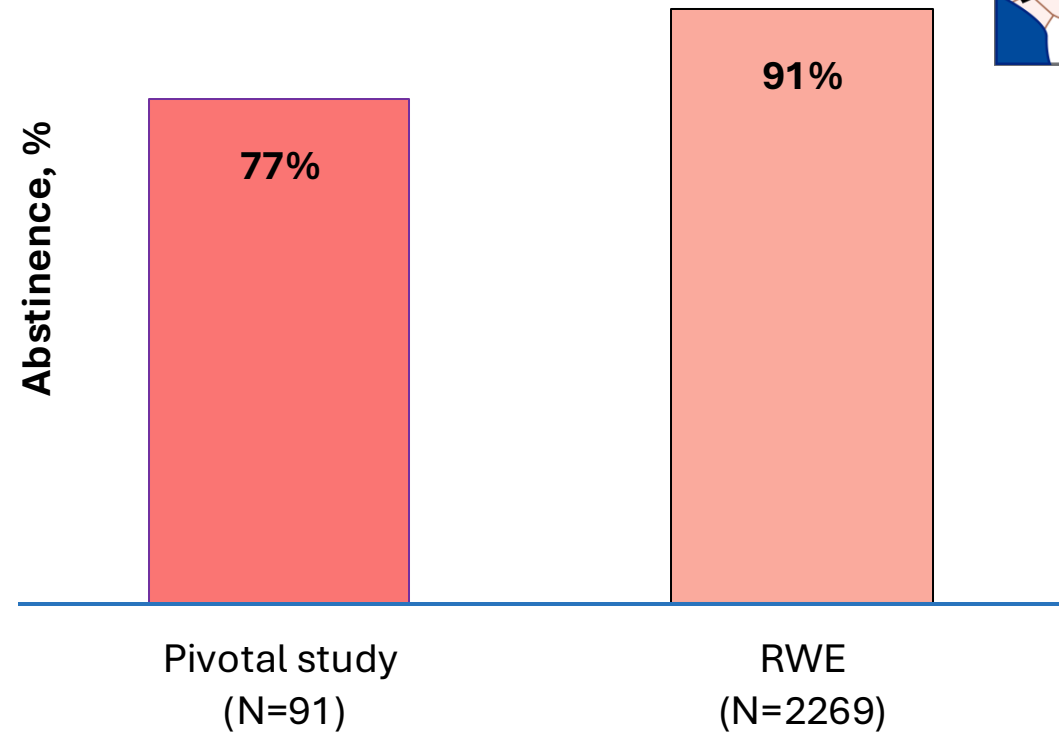
Intended to:
Increase abstinence from a patient's substance of abuse during treatment, and increase retention in an outpatient treatment program

RCT With mOUD and RWE Data for reSET-O

Increased Abstinence of Opioid Use in Weeks 9–12 *Pivotal Study*



Increased Abstinence of Opioid Use in Weeks 9–12 *Real-World Evidence*




mOUD, medication for opioid use disorder; RCT, randomized controlled trial; TAU, treatment as usual; RWE, real world evidence
TAU is an mOUD and a biweekly meeting with a clinician. Abstinence is measured through a urine drug screen.




Evidence of Benefits of reSET-O for OUD

Pivotal Study¹

*Real-World Evidence Shows
Healthcare Cost Reductions²*



**Higher retention
with PDT**



45% Reduction in
ED visits



**Low risk of
adverse events**



64% Reduction in
hospitalizations



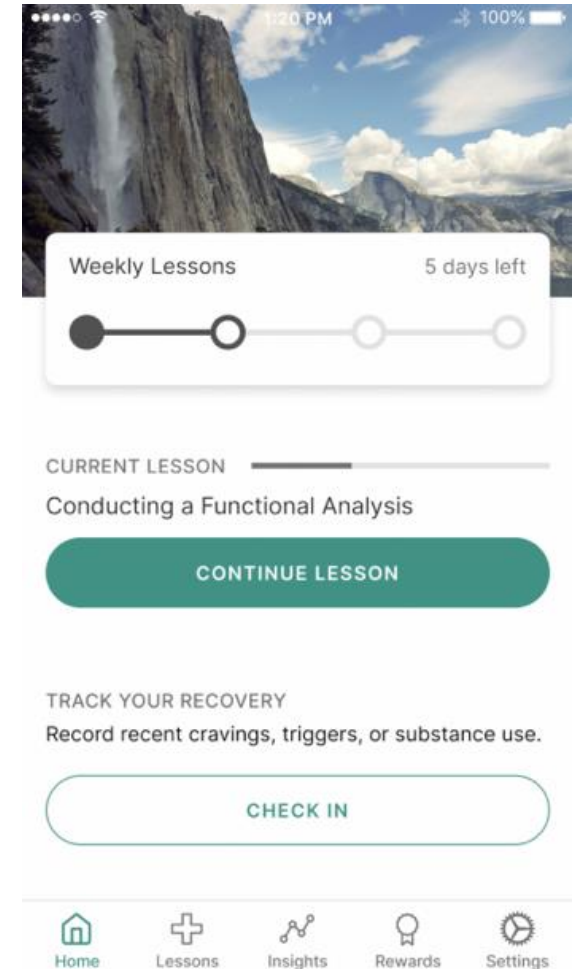
reSET-O for Opioid Use Disorder

- PDT for opioid use disorder (OUD) with 67 interactive modules with Community Reinforcement Approach lessons, training, and contingency management through rewards with voluntary buprenorphine check-in feature
- For patients 18 years or older who are currently under the supervision of a clinician

Intended to:

Increase retention of patients with OUD in outpatient treatment by providing cognitive behavioral therapy via mobile app

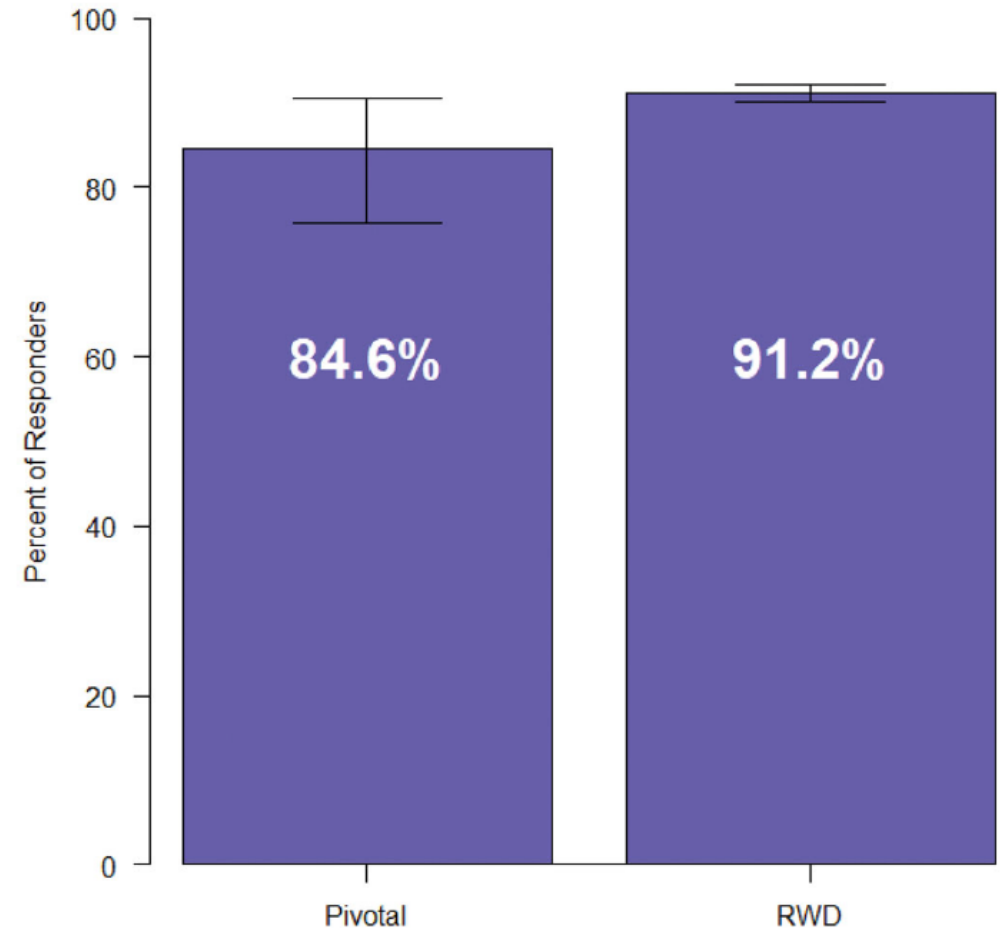
reSET-O user interface





Real-World Use of reSET-O for OUD

- Data from 3144 individuals with OUD instructed to complete 4 modules a week
- **48% completed all modules**, 65% completed half of all modules, 79% completed at least 8 of the 67 possible therapeutic modules
- 91% of patients met the responder definition of 80% of self-report or urine drug screen negative
- 74.2% of patients were retained through the first 12 weeks of treatment, 643 used 2nd prescription
- Results demonstrate that reSET-O is readily and broadly used by patients with OUD and that high real-world engagement is positively associated with abstinence and retention in treatment

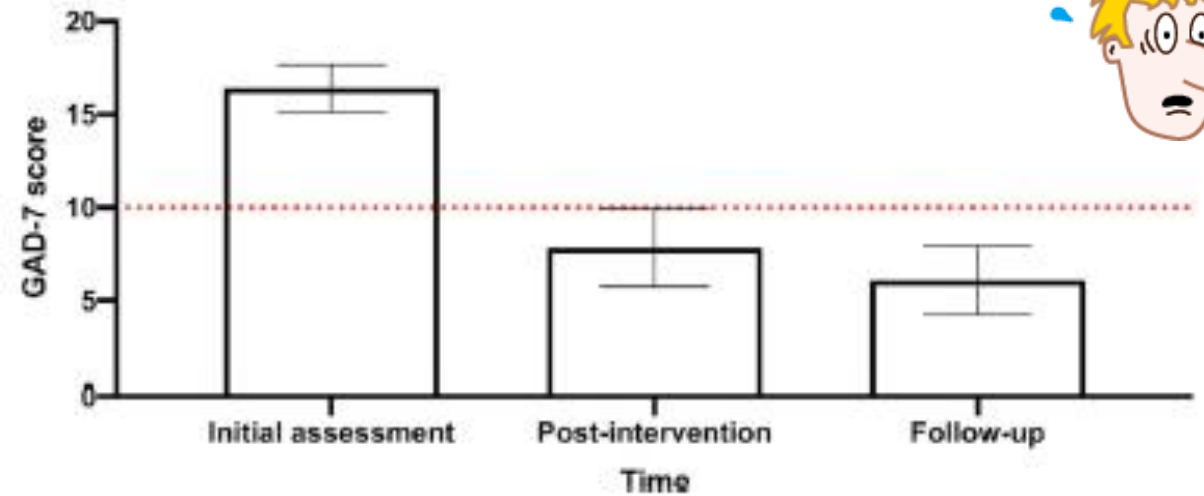


Responder analysis of $\geq 80\%$ negative urine drug screens or self-report. RWD: real-world data.

Daylight for Generalized Anxiety Disorder (GAD)

- Daylight is FDA cleared for managing anxiety
- Based on cognitive behavioral therapy and recommended to spend a minimum of 10 minutes per day
- In trials, 70% of participants no longer had clinically significant symptoms of GAD, 61% no longer had significant depressive symptoms, and 40% no longer had significant sleep difficulty

GAD-7 Scores Decrease After Daylight Use



Post-intervention 6 weeks, follow up 10 weeks post-intervention

Intended to:

Decrease the negative effects of generalized anxiety disorder

Tense and Release



Worry Time



Thought Challenger



Worry Exposure

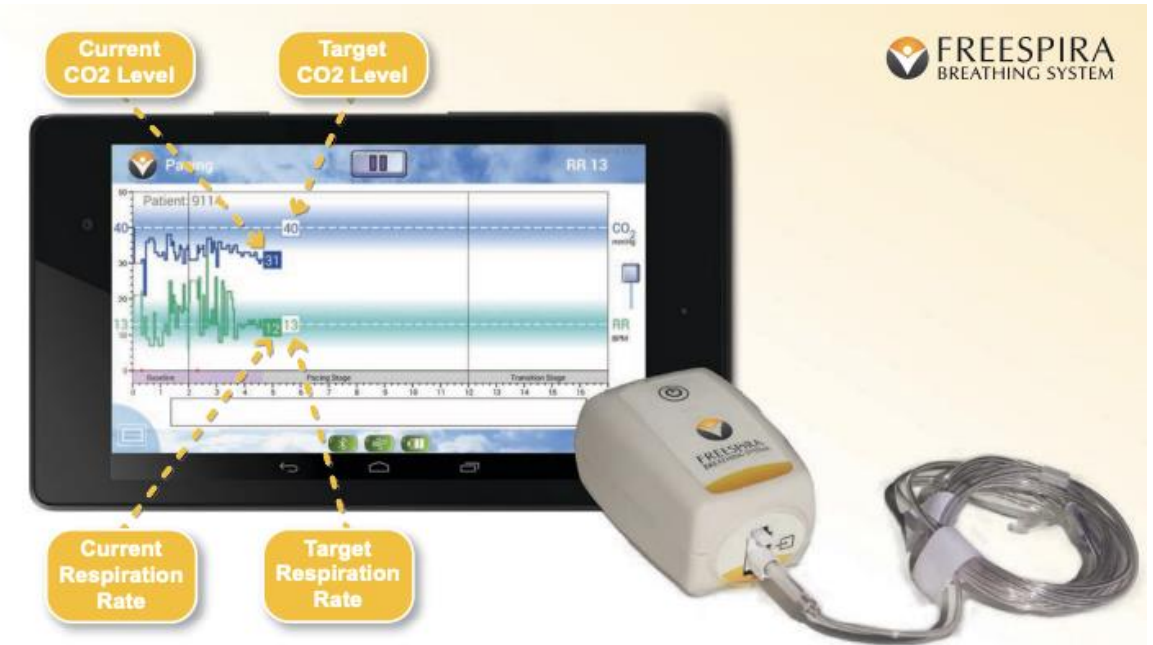




Freespira for Panic Disorder and PTSD

- Biofeedback device—Sensor and mobile app to measure and display exhaled carbon dioxide (EtCO₂) level and respiration rate (RR) in two 17-minute sessions/day
- Trains patients on how different breathing patterns affect EtCO₂ levels and RR
- Use as an adjunct for symptoms associated with panic disorder and/or PTSD

Freespira user interface and equipment



Intended to:

Use as a relaxation treatment for the reduction of stress by leading the user through guided and monitored breathing exercises





PRISM for PTSD

- Biofeedback—Laptop and cap sensor (>8 EEG channels) to measure biomarker termed amygdala-derived electrical fingerprint during 15–30-minute sessions to help train patients on how to control their amygdala activity
- Adults with PTSD as adjunct to standard care, to be used under direction of a healthcare professional in a clinical environment

Intended to:

Relax and decrease stress through the use of EEG biofeedback



Patients engage in non-trauma-based computer simulations to learn to regulate their PTSD symptoms

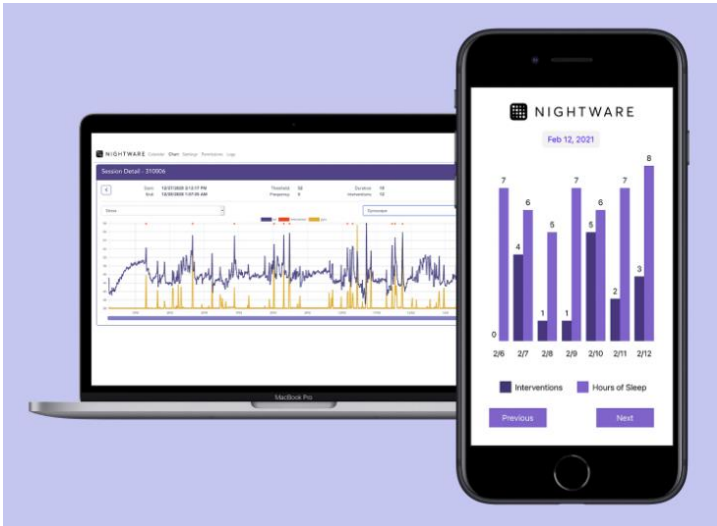


NightWare for PTSD-Associated Nightmares

- Apple Watch and iPhone sensors identify nightmares in real time and deliver brief vibrations to interrupt the nightmare without fully waking the patient
- Adults aged 22 years and older; avoid in those who “act out” during their nightmares (i.e., REM behavior disorder symptoms)

Intended to:
Provide temporary relief from sleep disturbances caused by nightmare disorder or nightmares from post-traumatic stress disorder (PTSD)

NightWare user interface



NightWare Digital Therapeutic Provider Instructions for Use. Accessed April 21, 2025. <https://nightware.com/wp-content/uploads/2021/08/NIGHTWARE-INSTRUCTIONS-FOR-USE-L.02-v2.pdf>.

EndeavorRx for ADHD



- Game-based PDT for children aged 8–12 years with ADHD (inattentive or combined type) for at-home play for 25 minutes per day, 5 days/week x 4 weeks
- Art, music, storytelling, and reward cycles provide sensory stimuli and motor challenges
- May not be appropriate for patients with photo-sensitive epilepsy, color blindness, and/or physical limitations

EndeavorRx user interface and equipment



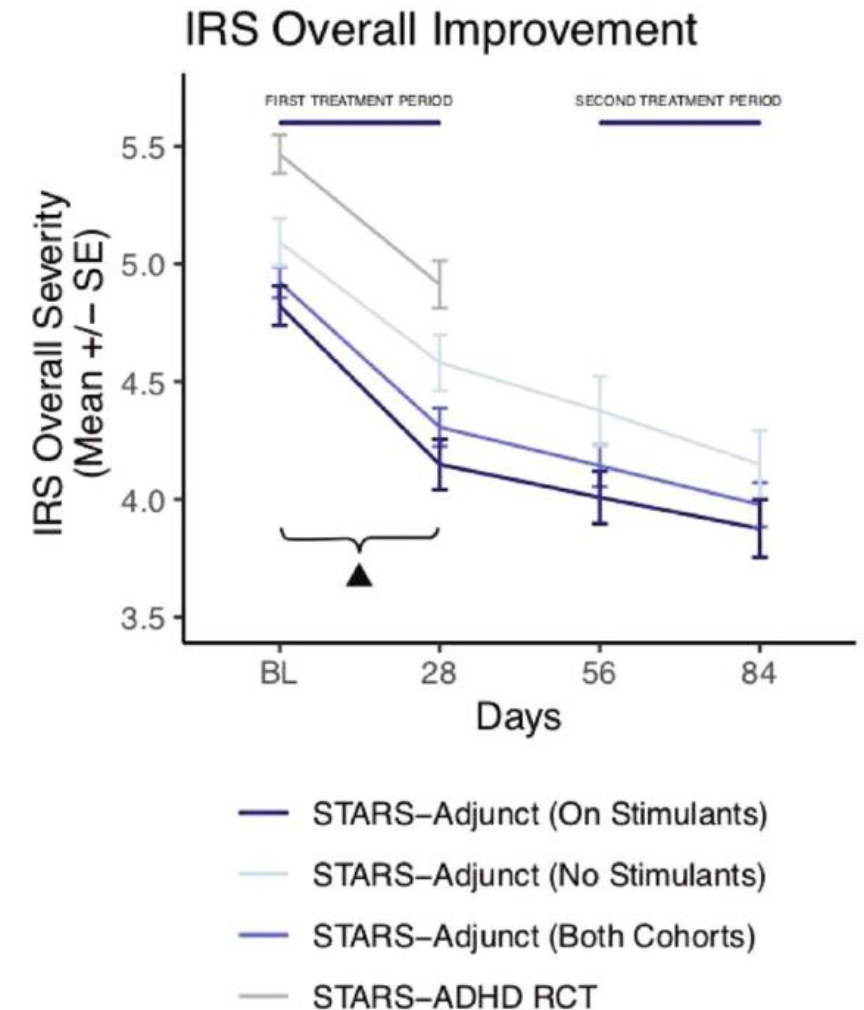
Intended to:

Enhance attention function, but not necessarily hyperactivity: use as part of a therapeutic program that may include clinician-directed therapy, medication, and/or educational programs

EndeavorRx in Children Taking Stimulants

- Open-label effectiveness study of EndeavorRx plus pharmacotherapy in 8–14-year-old children with ADHD on stimulant medication (n=130) or no stimulant medication (n=76)
- ADHD-related impairment improved in both groups after the first 4 weeks
- Adverse events included frustration (6.1%), headache (1.3%), dizziness (0.6%), emotional reaction (0.4%), nausea (0.4%), and aggression (0.2%); no serious adverse events

IRS: Impairment Rating Scale (primary outcome); RCT: randomized controlled trials; SE: standard error.



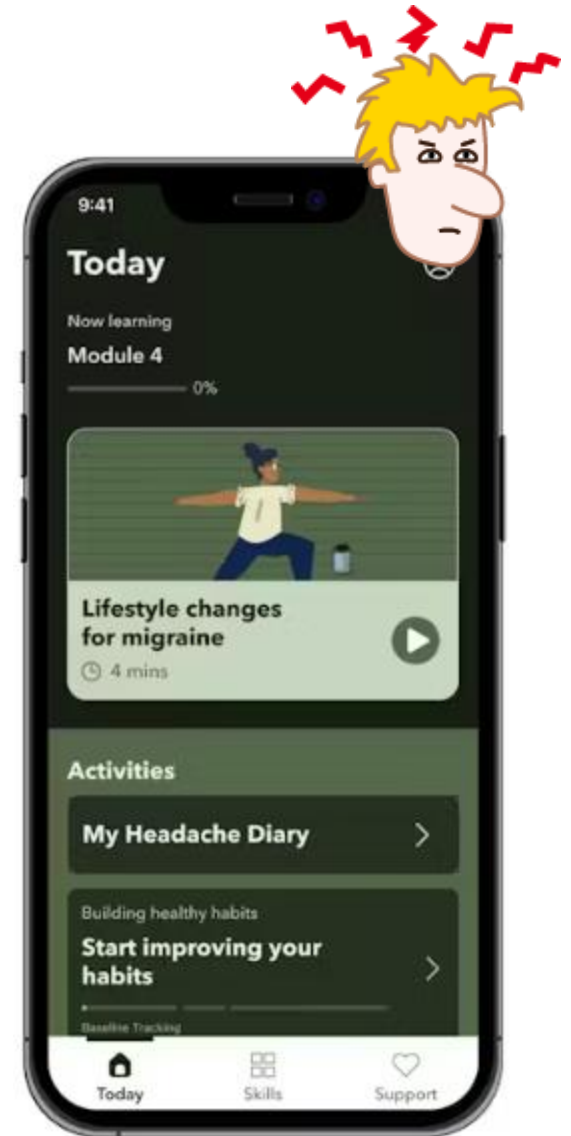
CT-132 for Episodic Migraine

- Indicated for the preventive treatment of episodic migraine in patients 18 years of age and older
- 12-week, app-based intervention that integrates multiple evidence-based behavioral techniques, including elements of cognitive behavioral therapy
- Proposed to modulate dysfunctional networks of sensory, autonomic, and affective neurocircuitry
- Meant to be available on any smartphone

Intended to:

Adjunctive treatment to strengthen neurolimbic circuitry to prevent future episodic migraines

CT-132 User Interface



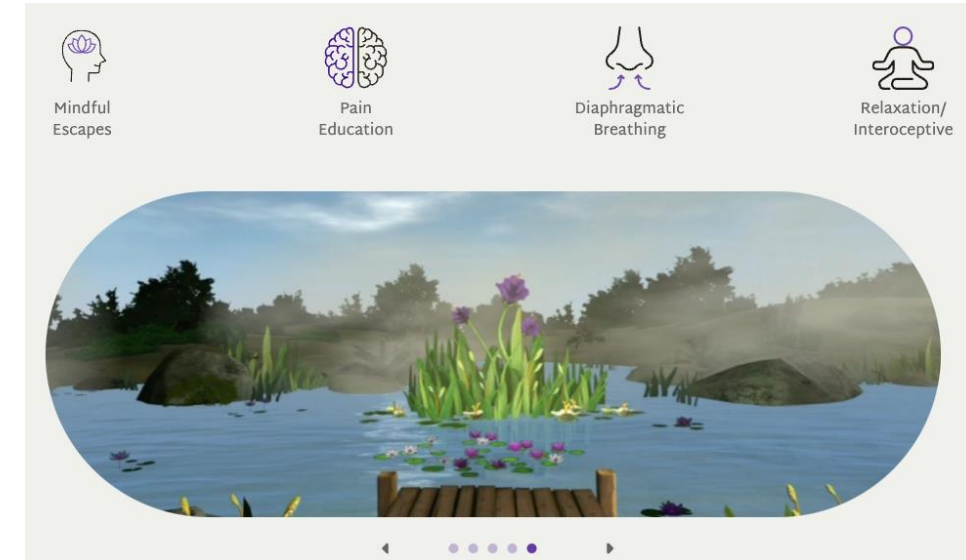
RelieVRx for Chronic Lower Back Pain (CLBP)

- First FDA-authorized adjunct treatment for CLBP aged 18+
- 8-week, immersive virtual reality intervention
- Integrates cognitive behavioral therapy, pain neuroscience education, diaphragmatic breathing, and mindfulness training
- Designed to retrain central pain processing and reduce pain interference by engaging sensory, emotional, and cognitive pain pathways
- Delivered through a VR headset and controller system for in-home use

Intended to:

Reduce pain intensity and interference, improve functional outcomes, and enhance quality of life in patients with chronic lower back pain

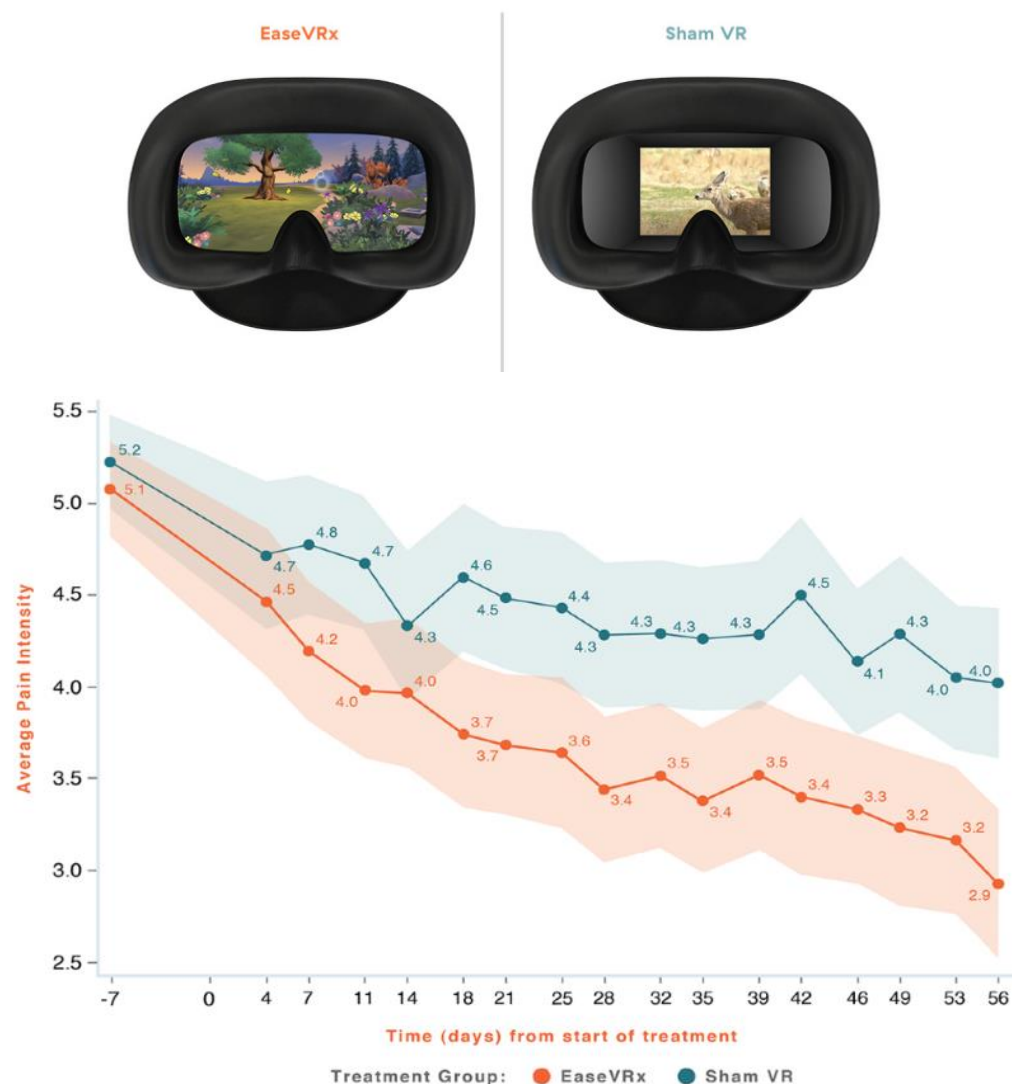
RelieVRx User Interface in VR Headset



RelieVRx for Chronic Lower Back Pain (CLBP)

- RelieVRx led to a **42.8% reduction in pain intensity** measured by the DVPRS vs 25.1% with sham VR
- Clinically meaningful improvements in pain interference with activity, mood, and stress
- Significantly improved physical function and reduced sleep disturbance
- 65% achieved $\geq 30\%$ pain reduction
- 46% achieved $\geq 50\%$ pain reduction
- High treatment engagement (90% completion)
- Decreased use of over-the-counter pain medications at 8 weeks (from 61 to 50 users $p=.01$; no reduction occurred in the sham group)

Average Pain Intensity = Defense and Veterans Pain Rating Scale (DVPRS)



Emerging Digital Therapeutics

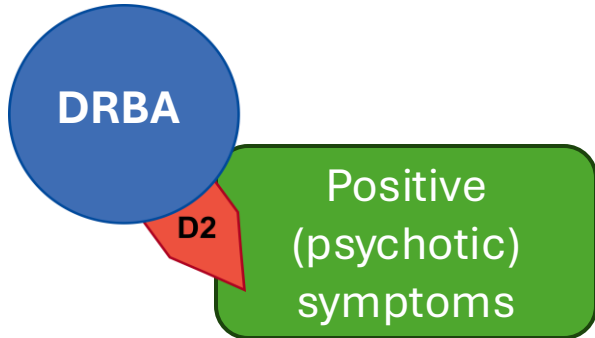
Clinical trials investigating emerging digital therapeutics for psychiatric disorders

NCT	Indication	DT Subtype	DT name
NCT05438160	Negative symptoms of schizophrenia	Mobile app	CT-155*
NCT03310281	Cognitive deficits in major depressive disorder	Video game	AKL-T03/09
NCT06003361	Major depressive disorder	Mobile app	BH-D-02
NCT05240794	Social anxiety disorder	Mobile app	ABM-01
NCT05809544	Insomnia	Mobile app	WCTP-I-B-02
NCT05710965	Attention-deficit/hyperactivity disorder	Device	FRx-001/3/4
NCT05748652	Generalized anxiety disorder	Mobile app	BH-D-01
NCT04948307	Opioid use disorder	Mobile app	OXD01
NCT05296473	Attention-deficit/hyperactivity disorder	Mobile app	CIP-013

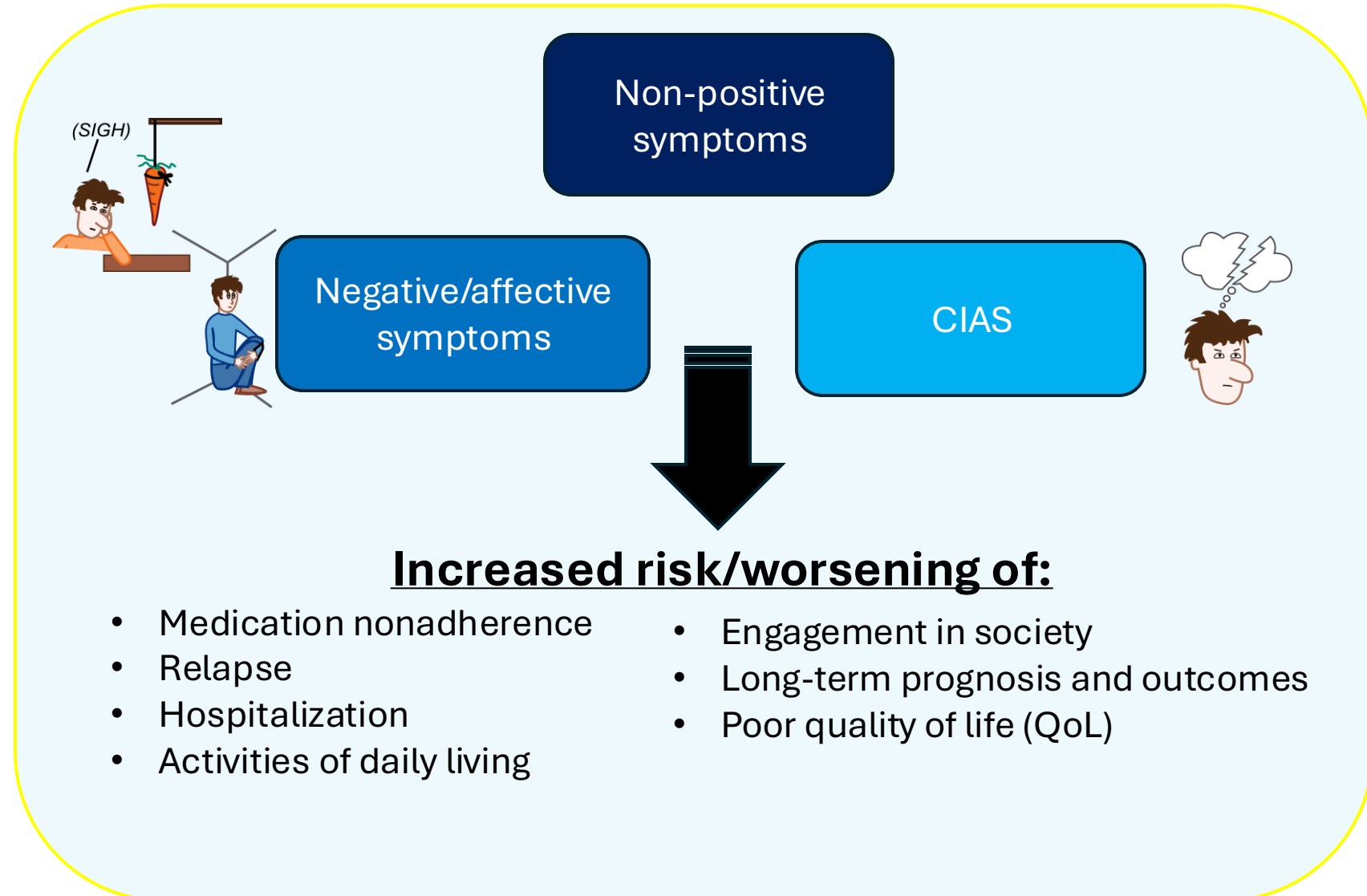
*Phase 3 CONVOKE trial underway, FDA Breakthrough
Device designation currently in place

DT = digital therapeutic

Negative and Cognitive Symptoms Have the Greatest Impact on Schizophrenia



- e.g.,
 - Hallucinations
 - Delusions
- Patients with schizophrenia experience **MORE**



Increased risk/worsening of:

- Medication nonadherence
- Relapse
- Hospitalization
- Activities of daily living
- Engagement in society
- Long-term prognosis and outcomes
- Poor quality of life (QoL)

CT-155 for Schizophrenia

- Being tested as an adjunct to antipsychotic medication in those with schizophrenia
- Targets negative symptoms
- Daily in-app activities during a 3-week orientation phase followed by an active 4-week phase
- Granted Breakthrough Device designation by the FDA in early 2024

Intended to:

Decrease negative symptoms of schizophrenia in those aged 18+



*Full CT-155 User Interface
Not Released*



Negative



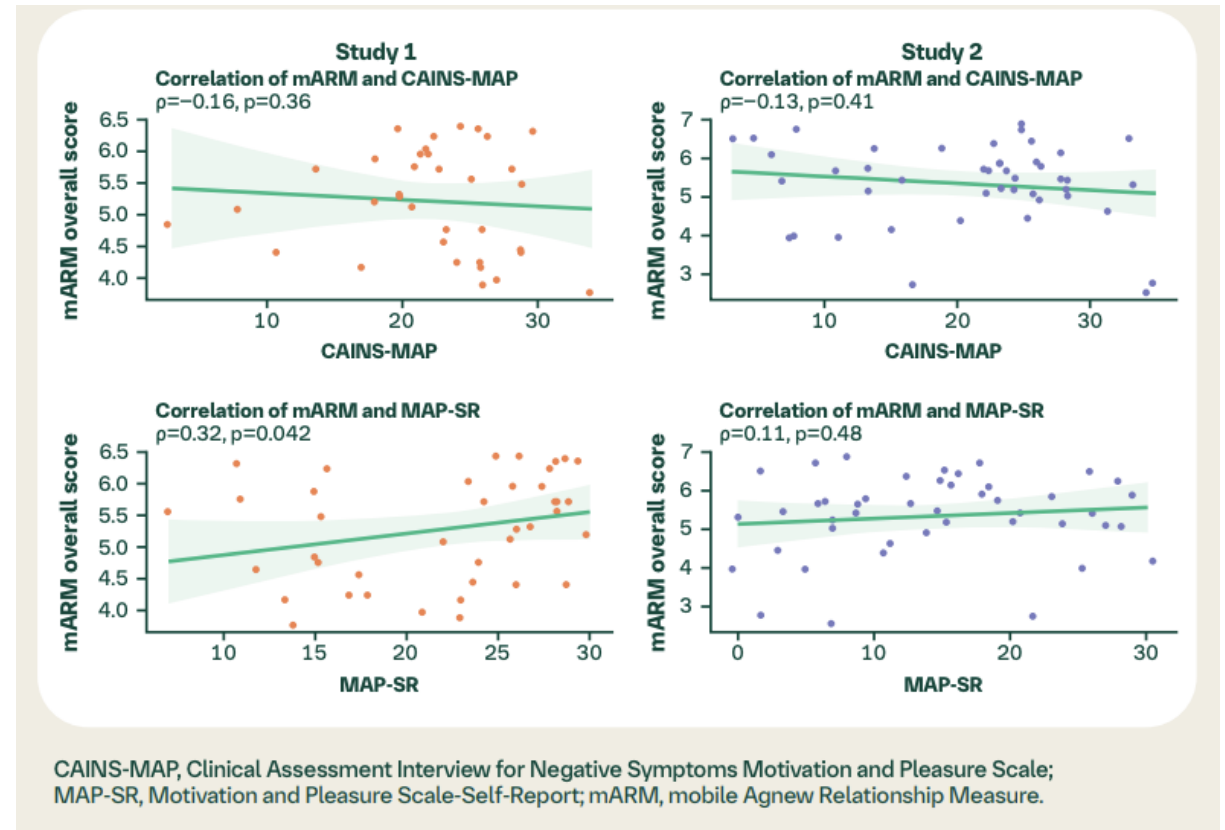
Symptoms



Digital Working Alliance (DWA) with CT-155 beta



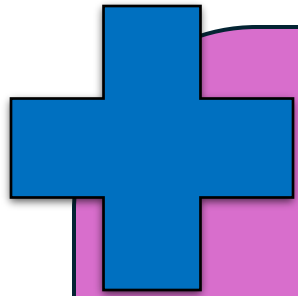
- A strong therapeutic alliance is critical for optimal therapeutic outcomes in schizophrenia
- Can patients with schizophrenia develop a therapeutic alliance with the CT-155 beta PDT?
- Daily in-app activities during a 3-week orientation phase (Study 1 & 2) followed by an active 4-week phase (Study 2)
- Patients formed (and maintained) a positive DWA (assessed using mARM) irrespective of negative symptom severity





Implementing PDTs in Practice

Pros and Cons of PDTs



Opportunities

- Provide non-drug options
- Improve patient outcomes
- Connect patients to providers
- Closer health data monitoring
- More convenient alternative to in-person care
- Can be culturally adapted

Challenges

- Can be more expensive and often not covered by insurance
- Concerns of data privacy and cybersecurity
- Relatively low clinical practice uptake
- Concerns of patient adherence

The Care Team and Software Features Can Increase Patient Engagement



Dedicated therapist support^{1,2}

- May help users set goals for PDT treatment
- Forms a therapeutic relationship



Peer support specialist²

- Has lived experience
- Is uniquely positioned to support patient use of PDTs



Digital navigator^{3,4}

- Is an expert who guide HCPs and institutions through the adoption and effective use of PDTs



Community support^{5,6}

- Peer-peer interactions, including group chats, to provide a sense of support



User-centric design^{5,6}

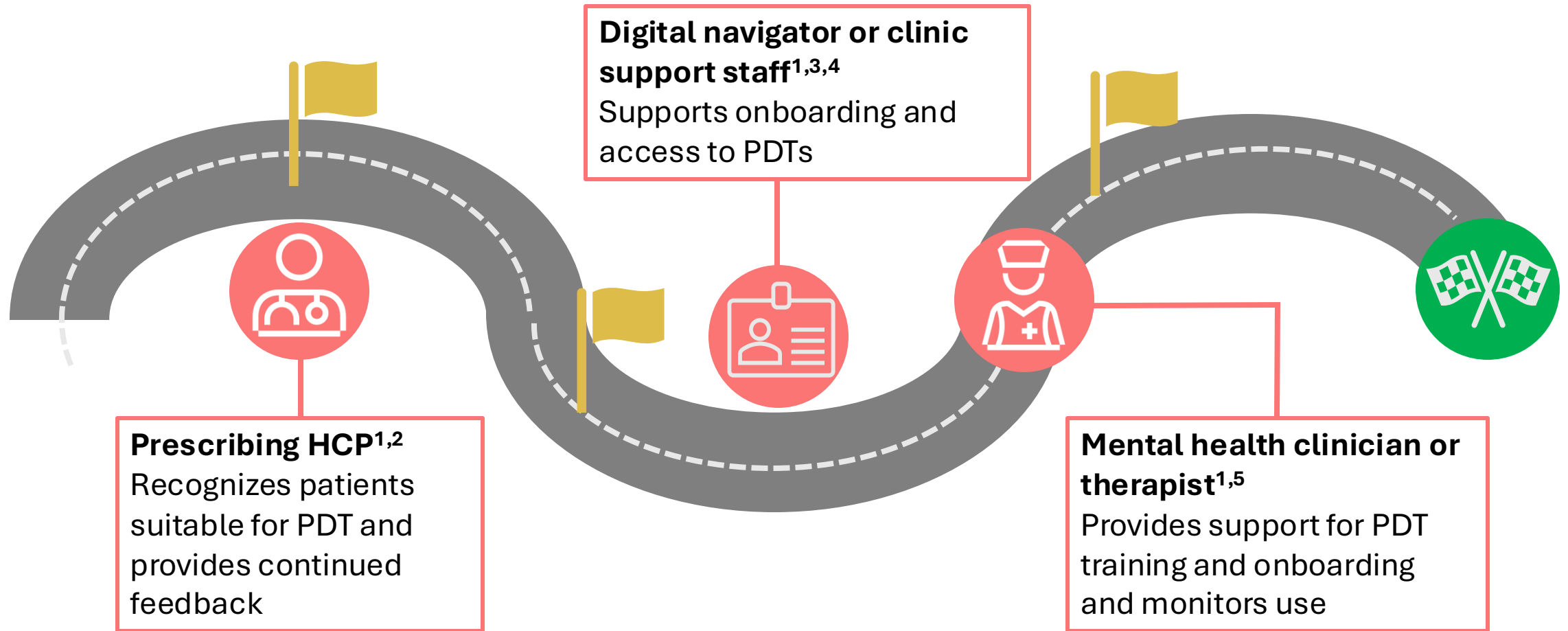
- Involvement of end users in the conception, design, and trialing of apps to increase app engagement



In-app patient support⁵

- Personalized feedback
- Reminders and push notifications
- Goal-setting features

Multidisciplinary Teams Help Facilitate the Use of PDTs



1. Ben-Zeev D et al. BMJ 2015;350:h945. 2. SAMHSA. Accessed February 2025. 3. NASMHPD. Accessed April 21, 2025. 4. Wisiewski H et al. Acta Psychiatr Scand 2020;141:350-5. 5. Hurley J et al. Int J Ment Health Nurs 2022;31:796-822.

Education and Training Are Critical

To implement PDTs in their practices, HCPs need:

Open communication with patients about the benefits



Improved knowledge of PDTs and their uses



Education on how PDTs impact workflow



Information regarding how PDTs affect HCP burden and burnout



An understanding of the PDT prescribing and reimbursement process

Practical Takeaways

- PDTs are digital platforms and are intended to be used in conjunction with standard care and under the supervision of a healthcare practitioner
- Available PDTs for psychiatric conditions have demonstrated improvements in symptom severity, functional outcomes, and treatment adherence when used alongside or independently of pharmacotherapy
- Real-world implementation is strengthened by multidisciplinary collaboration, including clinicians, digital navigators, and engaged patients
- Despite promising clinical outcomes, access remains limited due to low insurance coverage and gaps in provider education
- An expanding pipeline of PDTs is targeting unmet needs such as negative symptoms of schizophrenia, postpartum depression, and cognitive impairment



Q&A