

PEAR Therapeutics: reSET® and reSET-O®: For Addiction and Opioid Addiction

Vinfen Technology in Behavioral Health Conference

Innovation Panel: Developing Innovations in Digital Behavioral Healthcare

Audrey Kern, MD, DFASAM

Presented May 20, 2022



MEDICAL AFFAIRS

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Unless the context indicates otherwise, the terms “Pear,” “Company,” “we,” “us,” and “our” refer to Pear Therapeutics, Inc.

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FDA Authorization of PDTs Is Analogous to FDA Approval of Pharmaceuticals



	HEALTH AND WELLNESS APPS	PHARMACEUTICALS	PRESCRIPTION DIGITAL THERAPEUTICS
Utilizes digital technology to improve human health	✓		✓
Required testing in randomized controlled trials		✓	✓
FDA authorized safe and effective		✓	✓
Reimbursed via pharmacy/medical benefit		✓	✓
Provides real-time feedback to clinicians			✓



1900+
Small Molecules



1980+
Biologics

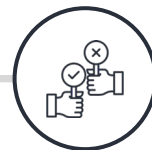


2000+
Cell/Gene Therapies



2017+
Prescription Digital Therapeutics

FDA Authorized PDTs: Pre- and Post-Market Authorization



Pivotal Clinical Trials¹

FDA Submission

FDA Review

FDA Decision

Post Market Surveillance

- Safety testing
- Efficacy testing

De Novo² or Premarket Notification (PMN) 510(k)³ Clearance

➤ For Pear's Currently Authorized Products:

21CFR882.5801 class 2 neurological therapeutic device with special controls (includes software verification, validation, and hazard analysis)

Clinical data must be provided to fulfill the following:

- Describe a validated model of behavioral therapy for the psychiatric disorder
- Validate the model of behavioral therapy as implemented by the device

➤ Requires clinical data to support reasonable assurance of the safety and effectiveness

Sponsors can petition to reclassify low- or moderate-risk devices that do not have predicates as De Novo

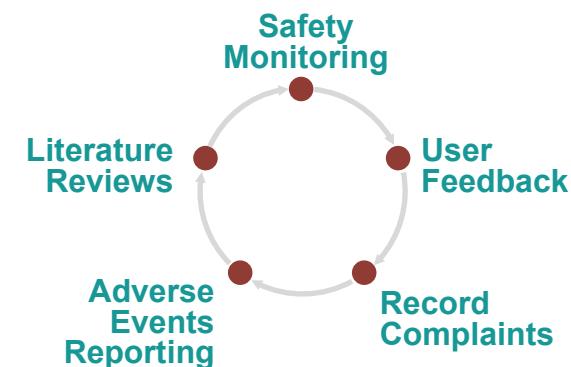
Devices approved as De Novo can then be predicates for others

➤ Product Examples

- reSET®: De Novo
- reSET-O®: 510(K)
- Somryst: 510(K)












FDA requires the continued monitoring of PDTs⁴

to evaluate the treatments' continued safety, effectiveness, and performance in real-world use.



1. Lee K., Bacchetti P., Sim I. Publication of Clinical Trials Supporting Successful New Drug Applications: A Literature Analysis. <https://doi.org/10.1371/journal.pmed.0050191>. Published September 23, 2008. Accessed September 23, 2021. 2. US Food and Drug Administration. De Novo Classification Request. <https://www.fda.gov/medical-devices/premarket-submissions/de-novo-classification-request>. Published November 20, 2019. Accessed September 23, 2021. 3. US Food and Drug Administration. Premarket Notification 510(k). <https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k>. Published March 13, 2020. Accessed September 23, 2021. 4. US Food and Drug Administration. Software as a Medical Device (SAMD): Clinical Evaluation. <https://www.fda.gov/media/100714/download>. Published December 8, 2017. Accessed October 2, 2020.

Pear Therapeutics Pipeline


	Product	Therapeutic Area / Indication	Development Stage				Content Partner
			Discovery	POC	Pivotal	Commercial	
Psychiatry	reSET	Substance Use Disorder	████████████████████				 Dartmouth*
	reSET-O	Opioid Use Disorder	████████████████████				 Dartmouth*
	Somryst	Chronic Insomnia	████████████████████				 UNIVERSITY of VIRGINIA
	Pear-009	Alcohol Use Disorder	██████████	██████████	██████████	██████████	
	Pear-004	Schizophrenia	██████████	██████████	██████████	██████████	
	Pear-011	Anxiety (GAD)	██████████	██████████	██████████	██████████	
	Pear-015	Depression (MDD)	██████████	██████████	██████████	██████████	 ISTITUTO AUXOLOGICO ITALIANO <small>Istituto di diagnosi e cure e laboratori scientifici</small>
Pear-017	Bipolar	██████████	██████████	██████████	██████████	 WAYPOINT HEALTH INNOVATIONS	
Pear-005	PTSD	██████████	██████████	██████████	██████████	 USC	
Neurology	Pear-010	Acute and Chronic Pain	██████████	██████████	██████████	██████████	 Firsthand TECHNOLOGY
	Pear-014	Migraine	██████████	██████████	██████████	██████████	 Cincinnati Children's <small>Medical Center</small>
	Pear-006	Multiple Sclerosis	██████████	██████████	██████████	██████████	
	Pear-013	Epilepsy	██████████	██████████	██████████	██████████	
Other	Pear-012	IBS	██████████	██████████	██████████	██████████	 Karolinska Institutet **
	Pear-018	Specialty GI	██████████	██████████	██████████	██████████	 Ironwood PHARMACEUTICALS ***
	Pear-016	Oncology	██████████	██████████	██████████	██████████	 Apricity HEALTH
	Pear-019	Cardiovascular	██████████	██████████	██████████	██████████	


Platform Enhancements

DIGITAL BIOMARKERS

Voice


Keystroke


Adherence Sensors


Physiologic Monitoring


*Dartmouth transaction is with a researcher employed by Dartmouth. Pear has no direct contractual relationship with Dartmouth relating to this content.

**Karolinska transaction is with individual researchers who are employed by the Karolinska Institute. Pear has no direct contractual relationship with the Karolinska Institute relating to this content.

***Services agreement with Ironwood to evaluate a PDT in GI diseases.

reSET® and reSET-O®: A New Paradigm in the treatment of Substance Use and Opioid Use Disorder



reSET Product Description



INDICATIONS FOR USE

reSET is intended to provide cognitive behavioral therapy, as an adjunct to a contingency management system, for patients 18 years of age and older, who are currently enrolled in outpatient treatment under the supervision of a clinician. reSET is indicated as a 12-week (90-day) prescription-only treatment for patients with substance use disorder (SUD) who are not currently on opioid replacement therapy, who do not abuse alcohol solely, or who do not abuse opioids as their primary substance of abuse.

It is intended to:

- Increase abstinence from a patient's substances of abuse during treatment, and
- Increase retention in the outpatient treatment program.

reSET-O Product Description



INDICATIONS FOR USE

reSET-O prescription digital therapeutic is a 12-week (84-day) software application intended to increase retention of patients with opioid use disorder (OUD) in outpatient treatment by providing cognitive behavioral therapy, as an adjunct to outpatient treatment that includes transmucosal buprenorphine and contingency management, for patients 18 years or older who are currently under the supervision of a clinician. reSET-O is indicated as a prescription-only digital therapeutic.

It is intended to:

- Increase retention in the outpatient treatment program.

This presentation does not include all the information needed to use reSET or reSET-O® safely and effectively. Please see full Directions for Use for complete Important Safety Information.

reSET and reSET-O Clinician Directions for Use. Pear Therapeutics. 2020

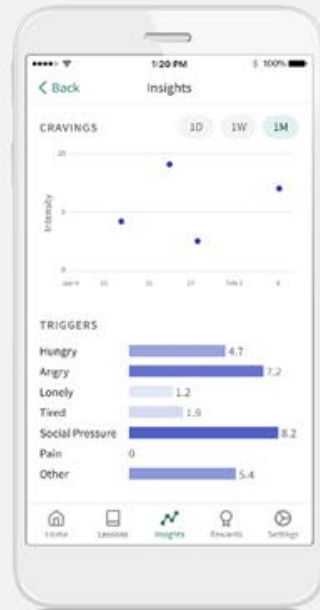
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Capabilities and Functionality

PATIENT

PROVIDES INTERVENTION^{1,2}

- Cognitive Behavioral Therapy (CBT) Modules
- Fluency Training
- Contingency Management
- Craving & Trigger Assessment



CLINICIAN

PROVIDES INSIGHTS^{3,4}

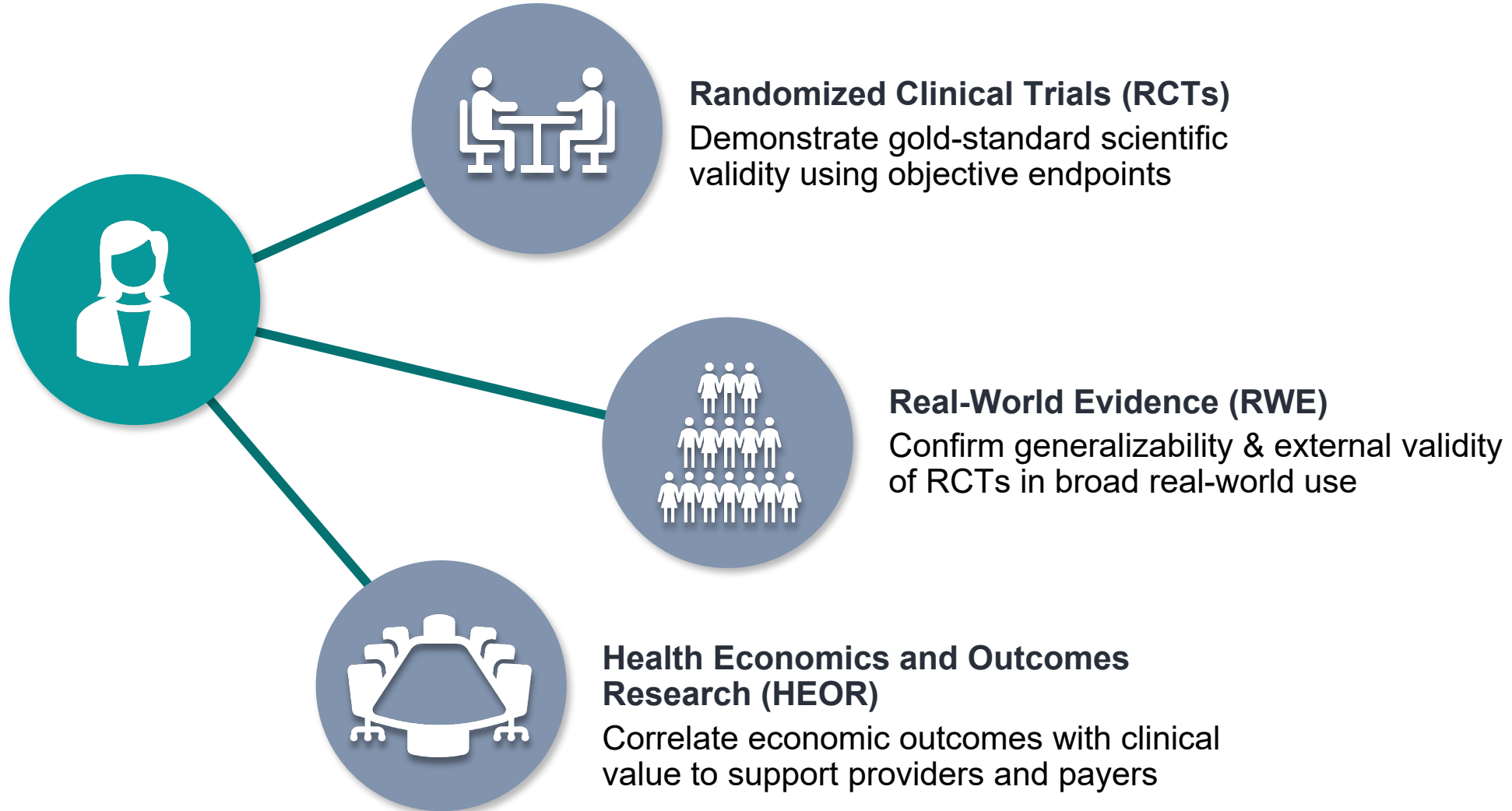
- Real-World Engagement
- CBT Module Use
- Fluency Training
- Contingency Management
- Cravings & Triggers
- Urine Drug Screens & Appointments



1. reSET® Patient Directions for Use. Boston, MA: Pear Therapeutics, Inc; 2019.
2. reSET-O® Patient Directions for Use. Boston, MA: Pear Therapeutics, Inc; 2019.

3. reSET® Clinician Directions for Use. Boston, MA: Pear Therapeutics, Inc; 2020.
4. reSET-O® Clinician Directions for Use. Boston, MA: Pear Therapeutics, Inc; 2020.

A Continuum of Evidence for reSET-O to Support Clinical Use, Policy and Decision Making

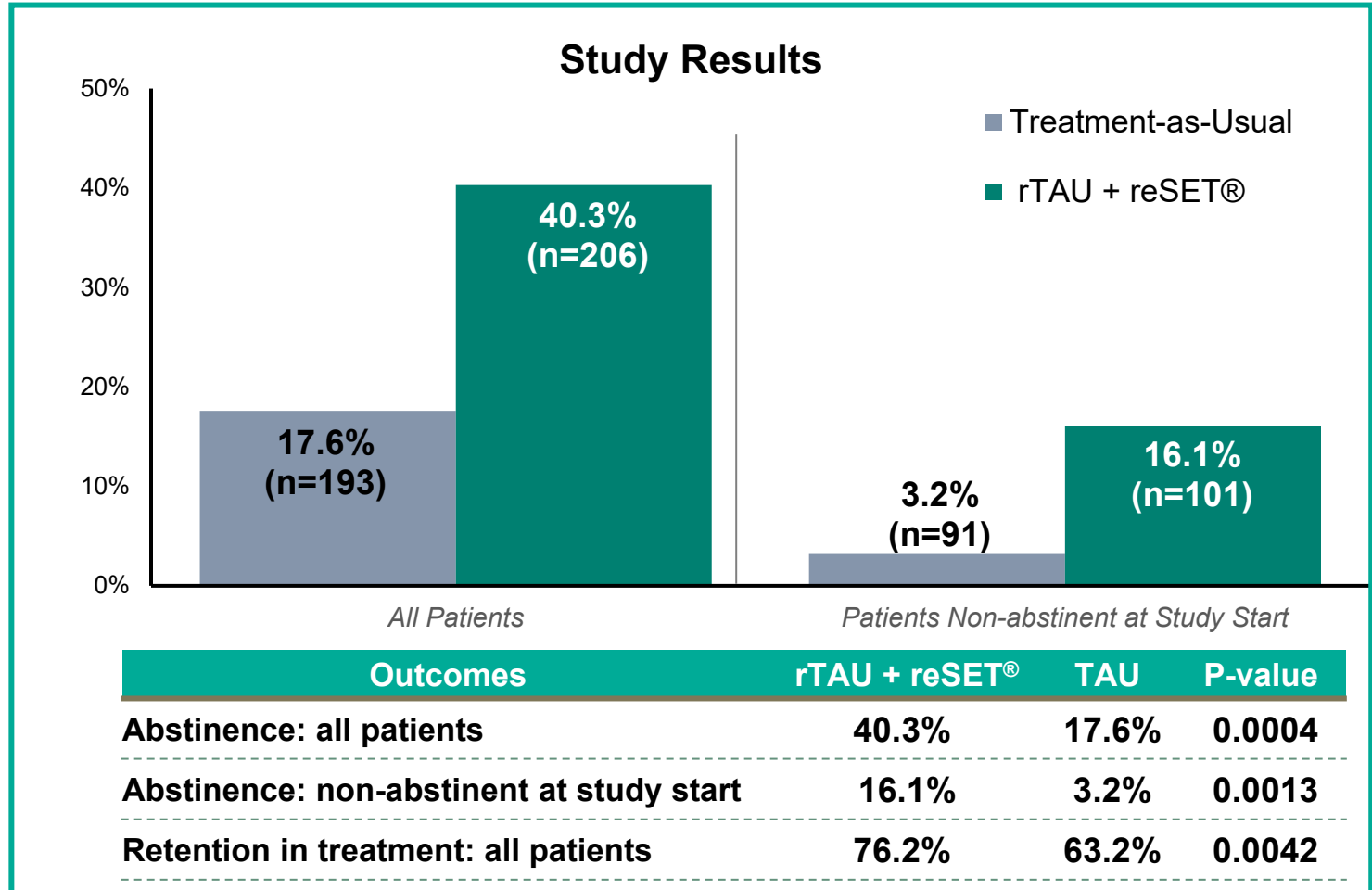


reSET® Clinical Data | Pivotal Trial Summary



Pivotal Trial Overview

- 399 patients with SUD (alcohol, cannabis, cocaine, stimulants) received either:
 - Treatment-as-Usual (TAU), consisting of intensive face-to-face therapy
 - Reduced TAU+reSET® (academic name Therapeutic Education System, or TES [rTAU+ reSET®]) for 12 weeks¹
- Patients provided urine samples twice per week to objectively monitor abstinence
- Co-primary study endpoints
 - Abstinence in weeks 9-12
 - Retention in treatment



Treatment with reSET did not demonstrate a significant difference in unanticipated adverse events compared to TAU

Campbell et al. American Journal of Psychiatry. 2014. 171(6):683-690; Pear Internal data and Pear regulatory submission. DEN160018

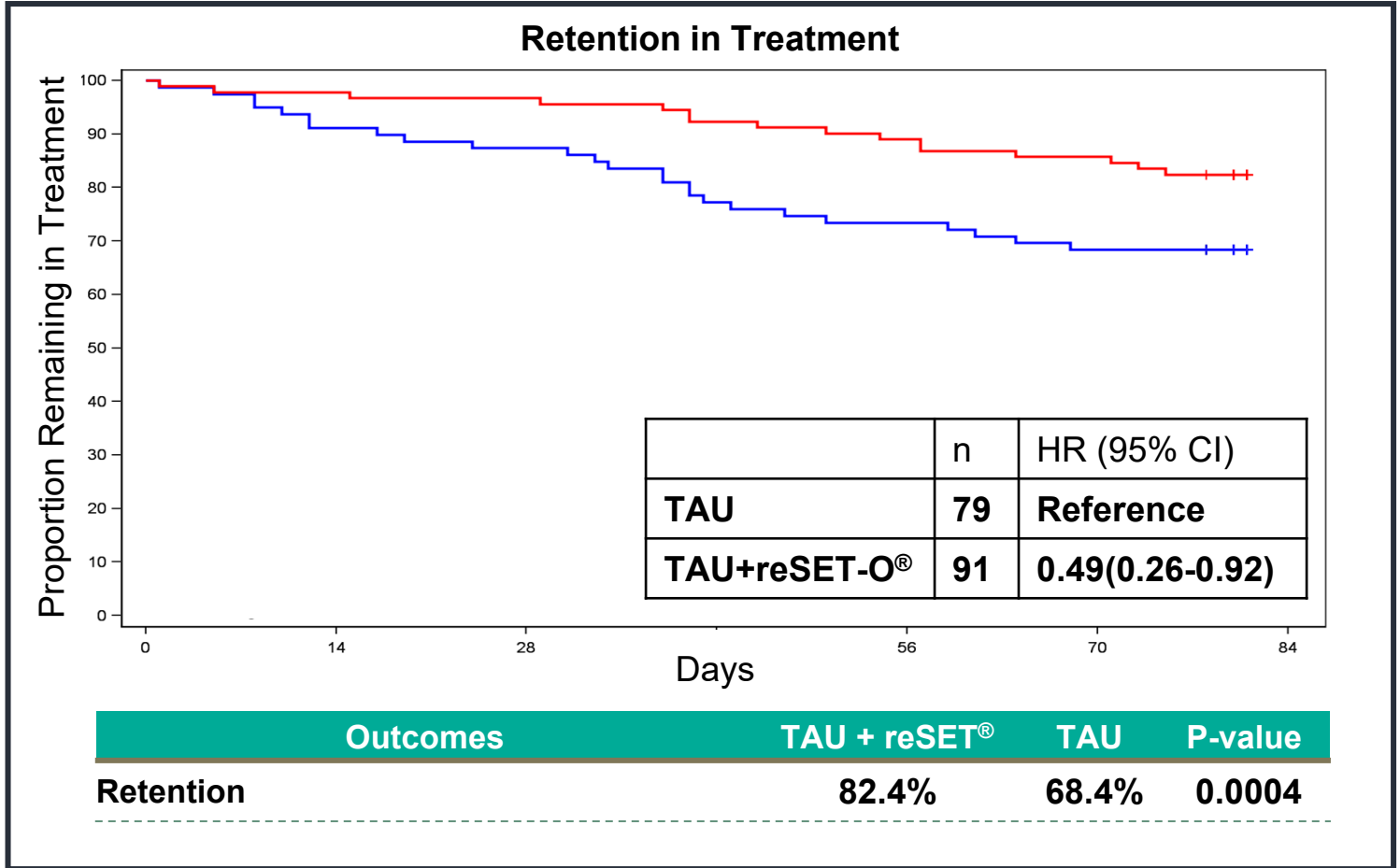
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reSET-O® Clinical Data | Pivotal Trial Summary



Pivotal Trial Overview

- 170 patients were randomized to receive either:
 - Treatment-as-Usual (TAU), consisting of Contingency Management + buprenorphine¹ or
 - TAU + reSET-O® (academic name Therapeutic Education System, or TES) + Contingency Management + buprenorphine
- All patients received 30 mins. of face-to-face counseling every other week.
- Primary endpoint analysis²
 - Retention in treatment



The observed adverse events were of a type and frequency as anticipated in a large population of patients with OUD or associated with buprenorphine pharmacotherapy, particularly during the induction phase. The adverse events observed were adjudicated to not be device related

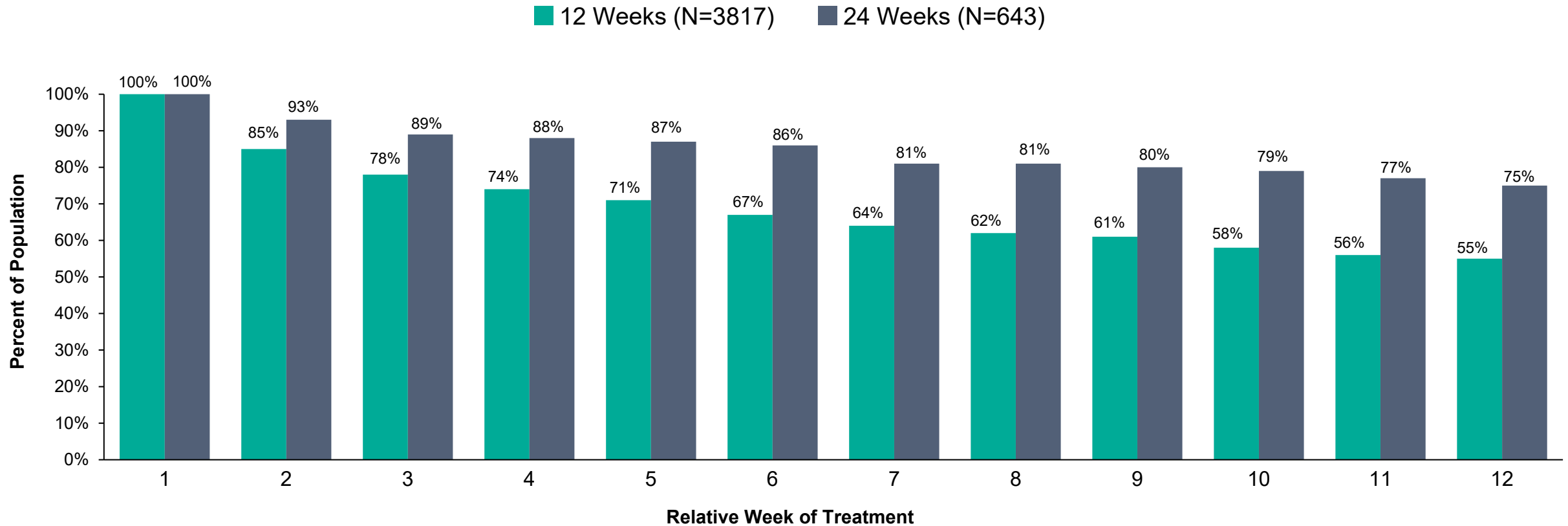
Christensen et al. J Consult Clin Psychol. 2014;82(6):964-972. doi:10.1037/a0037496; Pear regulatory submission. DEN160018hcf; Maricich YA, et al. Curr Med Res Opin. 2021; reSET-O Clinician Directions for Use. Boston, MA: Pear Therapeutics, Inc. 2020.

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A Majority of Patients Remain Active in reSET-O Through Week 12 of First and Second Prescriptions



Activity by Week



Activity was defined as patient use of any PDT feature on a given day

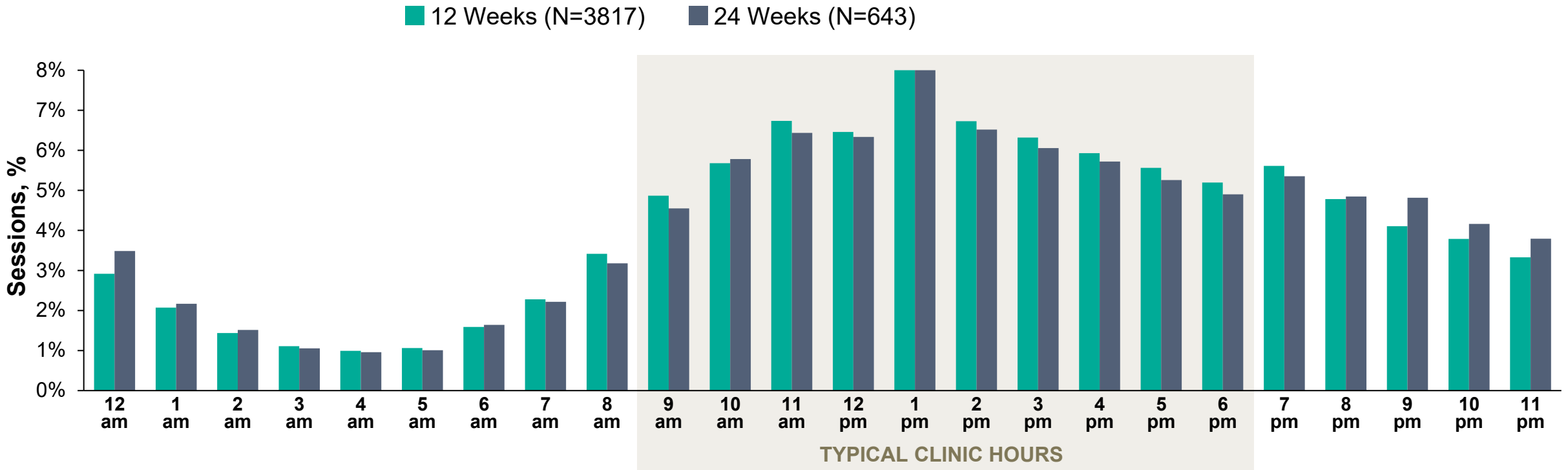
1. Maricich Y et al. Real-world use and clinical outcomes after 24 weeks of treatment with a prescription digital therapeutic for opioid use disorder. *Hospital Practice*. 2021.

<https://doi.org/10.1080/21548331.2021.1974243>

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Patients are active in reSET-O Throughout the Full 24-hour Period

Activity by Time of Day



- In each cohort approximately 60% of activity occurred during typical clinic hours
- Approximately 40% of activity occurred when treatment may be otherwise unavailable

Activity was defined as patient use of any PDT feature on a given day

1. Maricich Y et al. Real-world use and clinical outcomes after 24 weeks of treatment with a prescription digital therapeutic for opioid use disorder. *Hospital Practice*. 2021.

<https://doi.org/10.1080/21548331.2021.1974243>

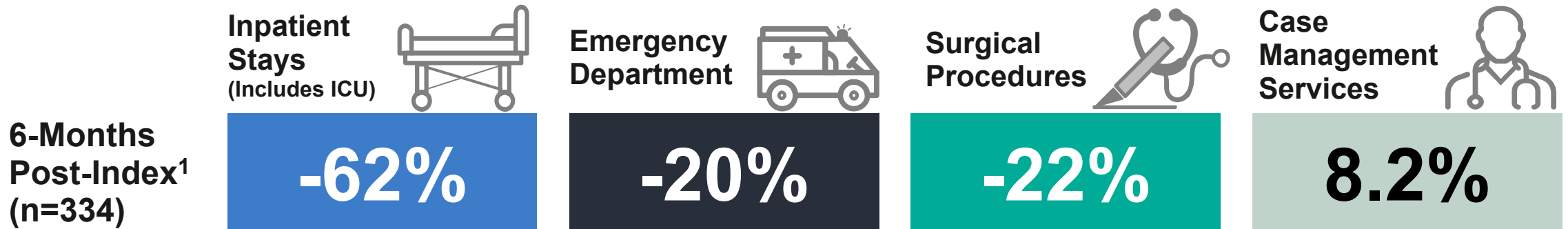
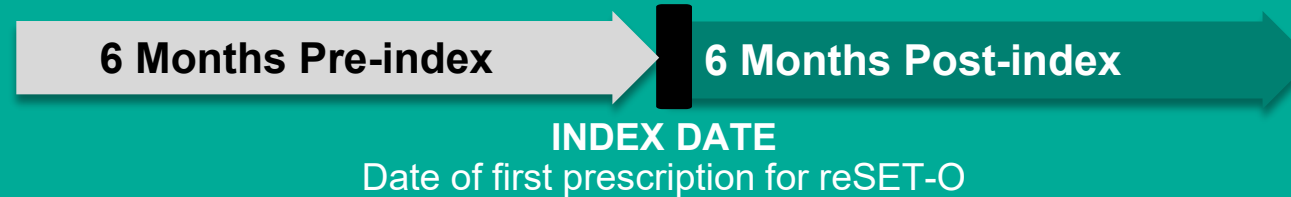
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reSET-O[®]: Reduced Healthcare Resource Utilization



Study Overviews^{1,2}

- A retrospective analysis of the HealthVerity PrivateSource 20 claims database was performed to assess the impact of reSET-O[®] initiation on healthcare resource utilization among patients receiving treatment for OUD
- Patients who activated reSET-O from a large representative database
- Comparison of healthcare resource utilization between baseline and study period including facility and clinician service encounters



Mean number of days in the pre-index and post-index period are 180.0 and 104.0, respectively. Incidence and IRR are evaluated from a repeated measures (ie, pre- and post-index for each patient) negative binomial model of count of stays/visits, with an offset for the number of days in each period

Pear cannot provide any assurance that you will experience similar reductions in healthcare resource utilization

1. Velez FF, et al. Expert Rev Pharmacoecon Outcomes Res. 2021.(1):69-76.

Pear is at the Center of Improving Health Equity



Pear prioritizes health equity and inclusion of diverse populations to ensure its PDTs benefit people with social determinants of health that historically have made meeting their mental health needs difficult.



All people with mental health needs are deserving of having those needs met and deserve to benefit from innovations such as PDTs. As such, Pear is committed to developing PDTs that address all populations.

Pear's SUD, OUD and insomnia therapeutics have been used in populations of women, people of color, rural populations, older individuals, and more, and have demonstrated benefits on addiction- and sleep-related outcomes.

These issues are at the forefront of how Pear is hoping to evolve the PDT arena. For instance, Pear launched Spanish versions of reSET and reSET-O in February 2022 and will be looking at outcome data in Spanish-speaking users as it becomes available.

INDICATIONS FOR USE:

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IMPORTANT SAFETY INFORMATION

Warnings: reSET is intended for patients whose primary language is English with a reading level of 7th grade or above, and who have access to an Android/iOS tablet or smartphone. reSET is intended only for patients who own a smartphone and are familiar with use of smartphone apps (applications).

Clinicians should not use reSET to communicate with their patients about emergency medical issues. Patients should be clearly instructed not to use reSET to communicate to their clinician any urgent or emergent information. In case of an emergency, patients should dial 911 or go to the nearest emergency room.

The long-term benefit of reSET has not been evaluated in studies lasting beyond 12 weeks (90 days) in the substance use disorder population. The ability of reSET to prevent potential relapse after therapy discontinuation has not been studied.

Please see the Clinician Brief Summary Instructions for reSET.



INDICATIONS FOR USE:

reSET-O is intended to increase retention of patients with opioid use disorder (OUD) in outpatient treatment by providing cognitive behavioral therapy, as an adjunct to outpatient treatment that includes transmucosal buprenorphine and contingency management, for patients 18 years or older who are currently under the supervision of a clinician. reSET-O is indicated as a prescription-only digital therapeutic.

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Clinicians should not use reSET-O to communicate with their patients about emergency medical issues. Patients should be clearly instructed not to use reSET-O to communicate to their clinician any urgent or emergent information. In case of an emergency, patients should dial 911 or go to the nearest emergency room.

reSET-O is not intended to be used as a stand-alone therapy for Opioid Use Disorder (OUD). reSET-O does not replace care by a licensed medical practitioner and is not intended to reduce the frequency or duration of in-person therapy. reSET-O does not represent a substitution for a patient's medication. Patients should continue to take their medications as directed by their healthcare provider.

Patients with opioid use disorder experience mental health disease and co-morbid medical problems at higher rates than the general population. Patients with opioid use disorder have higher baseline rates of suicidal ideation, and suicide attempts, and suicide completion. Clinicians should undertake standard of care to monitor patients for medical problems and mental health disease, including risk for harming others and/or themselves.

The long-term benefit of reSET-O has not been evaluated in studies lasting beyond 12 weeks (84 days) in the OUD population. The ability of reSET-O to prevent potential relapse after therapy discontinuation has not been studied.

Please see the Clinician Brief Summary Instructions for reSET-O.