National Institute on Drug Abuse
Advancing Addiction Science

NIDA Update

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Director, Division of Therapeutics and Medical Consequences

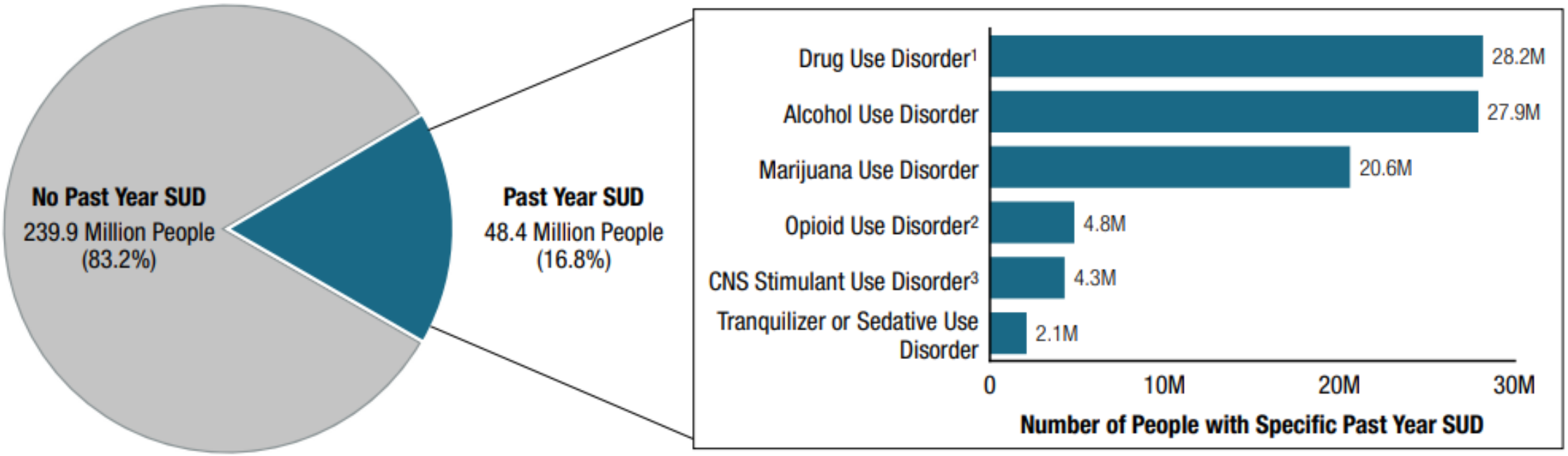
No conflicts of interest to disclose

NIDA BUDGET

(All dollars are in thousands)

	FY 2024 Operating Budget	FY 2025 Operating Budget	FY 2026 Operating Budget
Base	$1,308,070	$1,308,070	$1,308,070
HEAL	$355,295	$355,295	$355,295
Total	$1,663,365	$1,663,365	$1,663,365

Past Year Substance Use Disorder (SUD): Among People Aged 12 or Older; NSDUH, 2024



2024-2025: Provisional* Drug Overdose Deaths
12-month period ending in select months

	ALL DRUGS	HEROIN	NAT & SEMI SYNTHETIC	METHADONE	SYNTHETIC OPIOIDS (excluding methadone)	COCAINE	OTHER PSYCHO-STIMULANTS (meth.)
11/2024*	83,512	2,899	8,233	3,295	51,045	23,100	30,272
5/2025*	74,970	2,538	7,493	3,399	42,569	20,327	28,452
11/2025*	70,231	2,120	7,065	3,465	38,629	19,443	26,552
Percent Difference 11/24-11/25	**-15.90%**	**-26.87%**	**-14.19%**	**5.16%**	**-24.32%**	**-15.83%**	**-12.29%**

*NCHS Provisional drug-involved overdose death counts are ***predicted values***, 12 months ending in select months.

Source: Provisional Drug Overdose Death Counts produced by the National Vital Statistics System, NCHS, CDC, UHHS.

NIDA Strategic Planning

- NIH and ICs are required to submit strategic plans to Congress every 5 years, per the 21st Century Cures Act.

NIDA's Mission

Cite this article

NIDA's mission is to advance science on drug use and addiction and to apply that knowledge to improve individual and public health through:

- Strategically supporting and conducting basic, clinical, and epidemiological research on drug use, its consequences, and the underlying neurobiological, behavioral, and social mechanisms involved.
- Advancing the translation, effective implementation, and dissemination of scientific research findings to improve the prevention and treatment of SUDs, reduce adverse health consequences associated with drug use, and enhance public awareness of addiction as a chronic but treatable medical illness.

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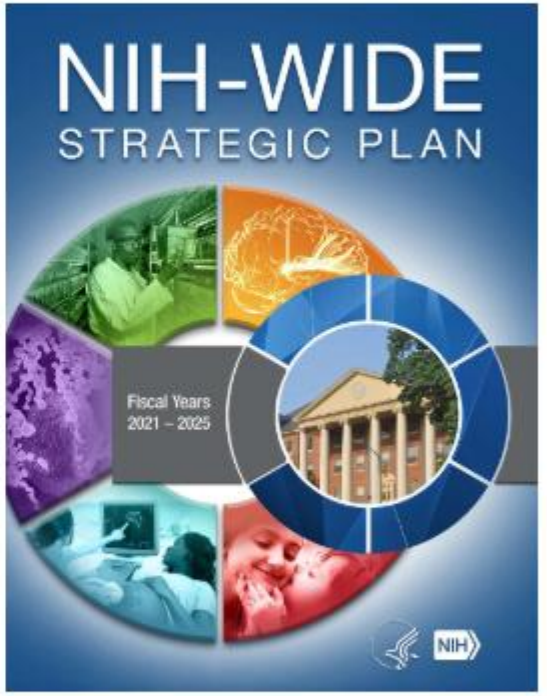
NIH-Wide Strategic Plan

About the Strategic Plan

In order to advance its mission and fulfill requirements of the *21st Century Cures Act*, NIH will update its Strategic Plan every 5 years. The most recent iteration, the *NIH-Wide Strategic Plan for Fiscal Years 2021–2025* PDF , is an update on the previous plan for fiscal years 2016–2020.

The Strategic Plan outlines NIH's vision for biomedical research direction, capacity, and stewardship, by articulating the highest priorities of NIH over the next 5 years. In addition, it provides illustrative examples of accomplishments under the last plan and new initiatives under this one. The Strategic Plan was developed through collaboration between leadership and staff across NIH and key stakeholders, including the research community, professional societies, advocacy groups, and the public.



The NIH-Wide Strategic Plan is designed to complement and harmonize Institute and Center (IC) strategic plans across NIH, which address their individual missions

- Communicates NIH research priorities to stakeholders and seeks their feedback.
- Does not set rules for decision-making about the NIH portfolio.

Seeking your input!

Request for Information: Inviting Input on NIDA's Strategic Plan for 2027-2031

Notice Number:
NOT-DA-26-014

Key Dates

Release Date:	
Response Date:	

Related Announcements

None

Issued by

National Institute on Drug Abuse (NIDA)

Purpose

Purpose

The National Institute on Drug Abuse (NIDA) seeks public input for its Strategic Plan for calendar years (CY) 2027-2031.

Background

The National Institute on Drug Abuse (NIDA) is the lead federal agency supporting research on drug use and its outcomes. NIDA's mission is to advance science on drug use and addiction and to apply that knowledge to improve individual and public health.

NIDA invites feedback on a draft outline for its CY 2027-2031 Strategic Plan, which will be an update to its current strategic plan (available at https://nida.nih.gov/about-nida/2022-2026-strategic-plan).

The strategic plan will focus on advancing scientific priorities across all facets of NIDA's scientific portfolio. It is intended to ensure that NIDA science meets current public health needs and takes advantage of new scientific opportunities to address emerging challenges related to substance use and

Request for Information (RFI): Inviting Comments and Suggestions on a Framework for the NIH-Wide Strategic Plan for Fiscal Years 2027-2031

Notice Number:
NOT-OD-26-047

Key Dates

Release Date:
March 16, 2026

Response Date:
May 26, 2026

Related Announcements

None

Issued by

Office of The Director, National Institutes of Health (OD)

Purpose

This Notice is a Request for Information (RFI) inviting feedback on the Framework for the NIH-Wide Strategic Plan for Fiscal Years 2027-2031 (FY27-FY31).

NOTE: It is important to read the entire RFI notice to ensure an adequate response is prepared to have a full understanding of how your response will be utilized.

Background

The purpose of the NIH-Wide Strategic Plan is to communicate how NIH will advance its mission to support research in pursuit of fundamental knowledge about the nature and behavior of living systems, and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.

Opioid Use Disorder and Overdose

Early Preclinical	Late Preclinical	Phase I Clinical Trials	Phase II Clinical Trials	Phase III Clinical Trials	New Formulation
▪ NTR1 modulator ▪ 5-HT2A/2C Agonist ▪ HBS087/HBS093 ▪ D-CYSee ▪ SBI-0801315/SBI-0799220 ▪ KOR Modulator ▪ MOR selective antagonist ▪ NAM368 ▪ Fentanyl/heroin vaccine	▪ AT-121 ▪ TRN-228 ▪ VVZ-2417 ▪ Oxytocin ▪ CS-1103 ▪ Methocinnamox ▪ MOR modulator ▪ GM-3009 (Oxa-iboga analog) ▪ SBS-226 ▪ DMX-101 ▪ M-KLH (Heroin Vaccine) ▪ Fentanyl vaccine ▪ Fentanyl mAb ▪ MG001 (Mitragynine)	▪ Oxytocin ▪ Cannabidiol ▪ VK4-116 ▪ CVL-354 ▪ AZD4041 ▪ KNX100 ▪ EC5026 ▪ SBS-147 ▪ Kindolor ▪ MEB-1170 ▪ NRS-033 ▪ EPD-2520 ▪ Oxycodone vaccine	▪ Cannabidiol ▪ Pregabalin + Lofexidine ▪ Suvorexant ▪ Ketamine ▪ Semaglutide ▪ Semaglutide ▪ Psilocybin ▪ Buprenorphine + Naltrexone ▪ Buprenorphine (OD) ▪ Buprenorphine (ED) ▪ Buprenorphine (LDI) ▪ INDV-2000 ▪ CSX-1004	▪ Suvorexant	▪ Naltrexone 2-month injection ▪ BICX104 (Naltrexone 3-month implant) ▪ OLANI (Naltrexone 6-month implant) ▪ BIOPIN 6 (Naltrexone 6-month implant) ▪ Naltrexone transdermal patch (NNTP) ▪ Nalmefene implant ▪ PF614-MPAR (Nafamostat/Oxycodone ADF) ▪ Buprenorphine ≥3-month injection ▪ Buprenorphine 6-month implant

https://nida.nih.gov/about-nida/organization/divisions/division-therapeutics-medical-consequences-dtmc

Stimulant Use Disorder and Overdose

Early Preclinical	Late Preclinical	Clinical Trials		
		Phase I	Phase II	Phase III
▪ SBI-0801315/SBI-0799220 ▪ SBS-518	▪ OMS 182399 ▪ PPL-138 ▪ NHB 1109 ▪ CocH5-Fc(M6)	▪ CS-1103 ▪ Exenatide ▪ BICX104/Bupropion ▪ STP-7-Mavoglurant ▪ Troriluzole ▪ Pentoxifylline ▪ Psilocybin ▪ Semaglutide	▪ Semaglutide ▪ Bupropion/Naltrexone	

https://nida.nih.gov/about-nida/organization/divisions/division-therapeutics-medical-consequences-dtmc

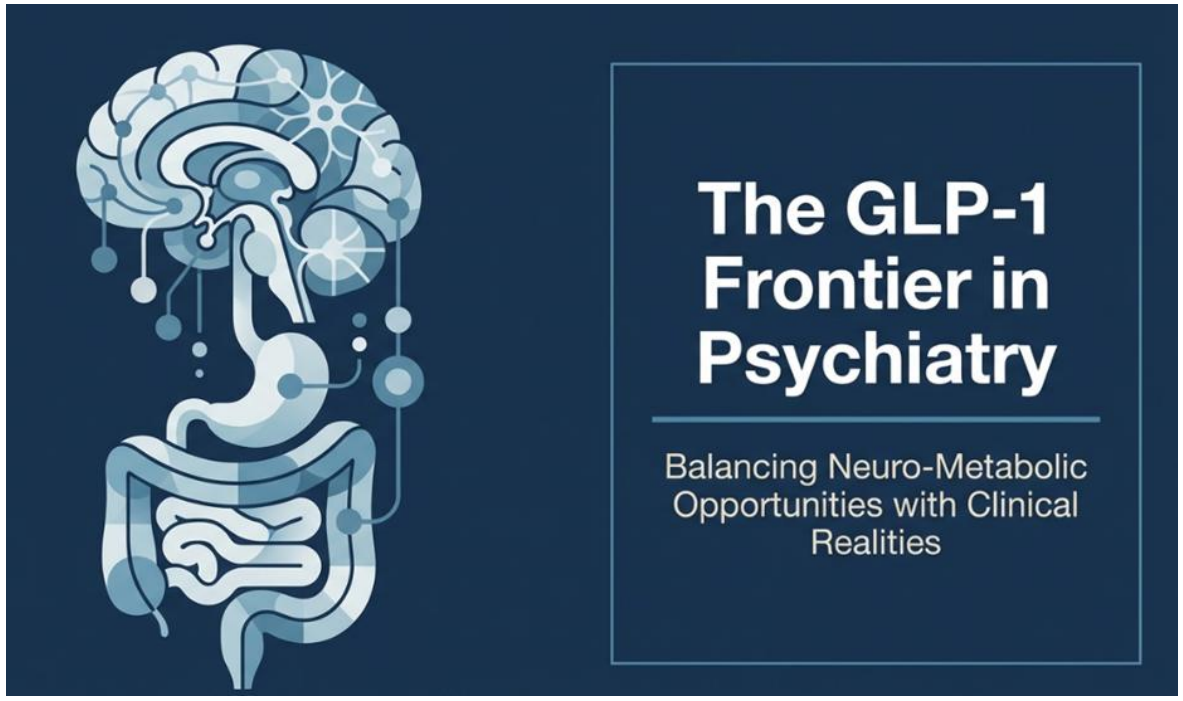
Cannabis Use Disorder

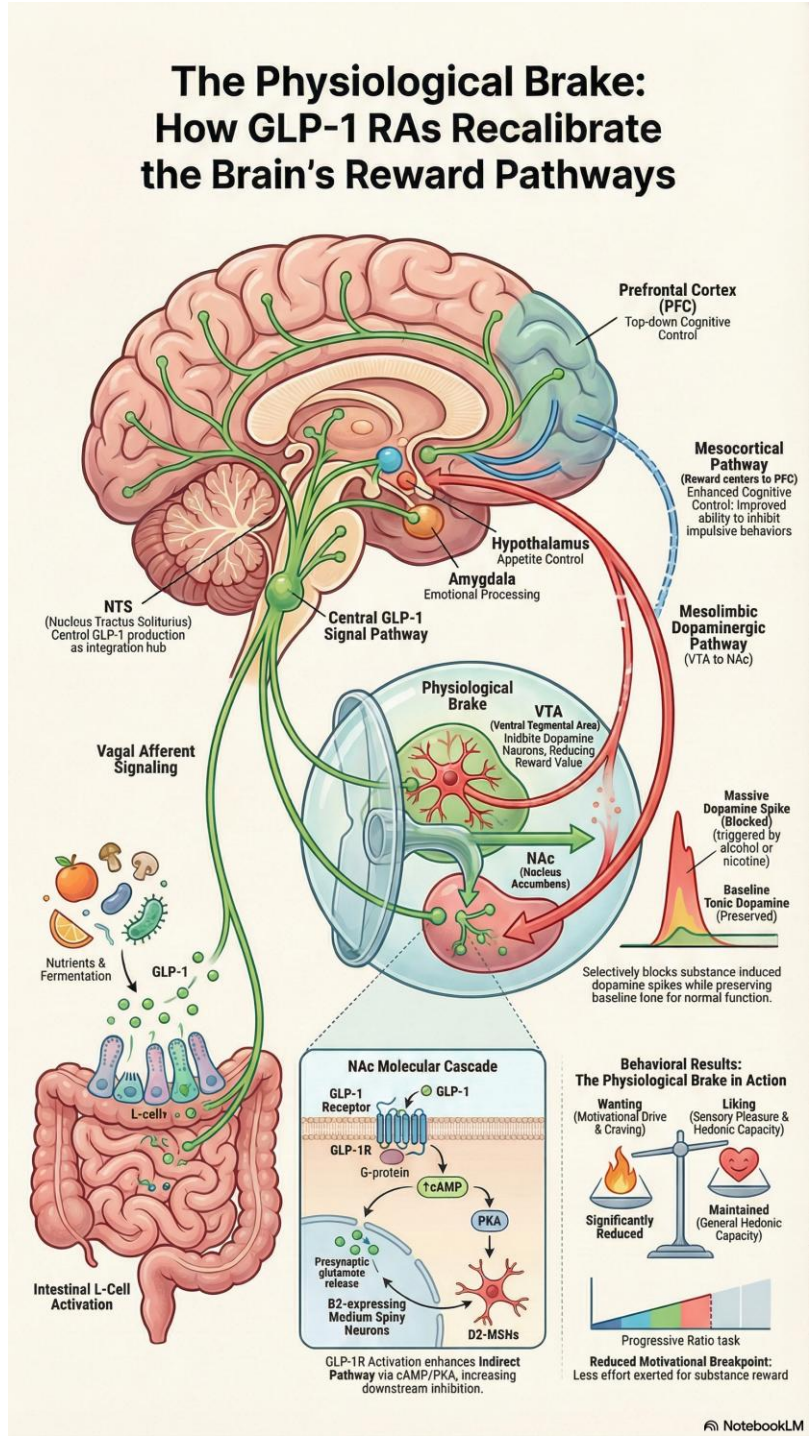
Early Preclinical	Late Preclinical	Clinical Trials		
		Phase I	Phase II	Phase III
		▪ Selonabant	▪ Cannabidiol/Hemp-derived cannabinoids	

Tobacco Use Disorder

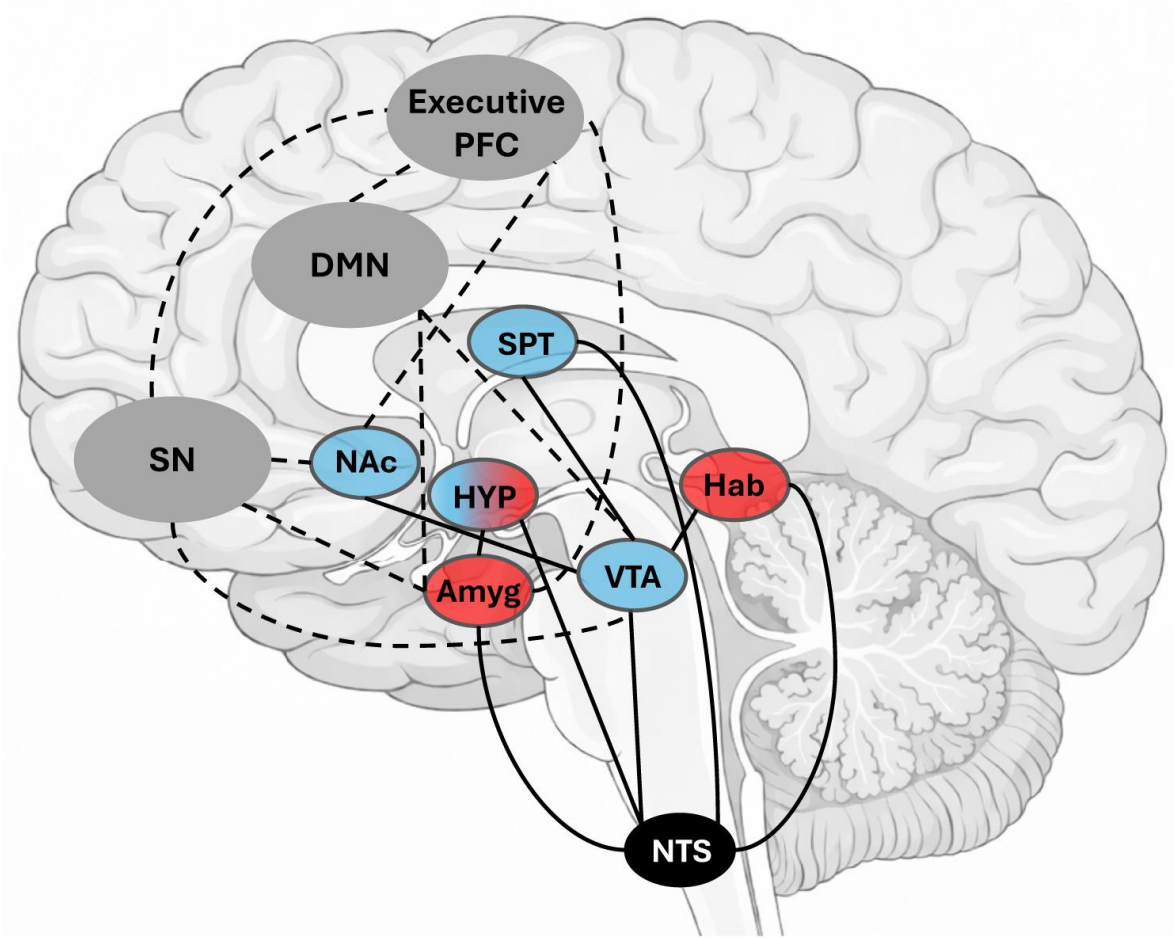
Early Preclinical	Late Preclinical	Clinical Trials		
		Phase I	Phase II	Phase III
	▪ ATI-1013 (anti-nicotine monoclonal antibody)	▪ AT-1082 (α3β4 partial agonist) ▪ Tetrahydrocannabivarin ▪ mGlu2 PAM SBP-9330	▪ Exenatide + NRT ▪ Tirzepatide+NRT	

https://nida.nih.gov/about-nida/organization/divisions/division-therapeutics-medical-consequences-dtmc


The GLP-1 Frontier in Psychiatry
Balancing Neuro-Metabolic Opportunities with Clinical Realities


The Physiological Brake: How GLP-1 RAs Recalibrate the Brain's Reward Pathways
Prefrontal Cortex (PFC)
Top-down Cognitive Control
Mesocortical Pathway
(Reward centers to PFC)
Enhanced Cognitive Control: Improved ability to inhibit impulsive behaviors
Hypothalamus
Appetite Control
Amygdala
Emotional Processing
NTS
(Nucleus Tractus Solitarius)
Control GLP-1 production as integration hub
Central GLP-1 Signal Pathway
Mesolimbic Dopaminergic Pathway
(VTA to NAc)
Physiological Brake
VTA
(Ventral Tegmental Area)
Inidbite Dopamine Naurons, Reducing Reward Value
Vagal Afferent Signaling
Massive Dopamine Spike (Blocked)
(triggered by alcohol or nicotine)
Baseline Tonic Dopamine
(Preserved)
NAc
(Nucleus Accumbens)
Nutrients & Fermentation
GLP-1
Selectively blocks substance induced dopamine spikes while preserving baseline lone for normal function.
L-cell
Intestinal L-Cell Activation
NAc Molecular Cascade
GLP-1
GLP-1 Receptor
GLP-1R
G-protein
↑cAMP
PKA
Presynaptic glutamote release
B2-expressing Medium Spiny Neurons
D2-MSNs
GLP-1R Activation enhances Indirect Pathway via cAMP/PKA, increasing downstream inhibition.
Behavioral Results: The Physiological Brake in Action
Wanting
(Motivational Drive & Craving)
Liking
(Sensory Pleasure & Hedonic Capacity)
Significantly Reduced
Maintained
(General Hedonic Capacity)
Progressive Ratio task
Reduced Motivational Breakpoint:
Less effort exerted for substance reward
NotebookLM

GLP-1RAs modulate positive and negative reinforcement, engaging saliency, interoceptive, and executive control networks



The PFC is necessary for decision making and self-Regulation. The saliency network (SN) is necessary for assigning incentive salience. The DMN processes interoceptive signals.

Positive reinforcement, binge/intoxication stage

Negative reinforcement, negative affect/ withdrawal stage

Color scheme consistent with prior addiction neurocircuitry/cycle figures
- Blue = positive reinforcement, matching circuitry coloring for binge/intoxication stage
- Red = negative reinforcement, matching circuitry coloring for negative affect/withdrawal stage

Dashed lines = connections from positive/negative cores to networks

Volkow et al. Biol Psychiatry. Jan. 2026

Opioid Use Disorder

- Preclinical
  - ↓ Heroin, fentanyl, and oxycodone self-administration and reinstatement (cue-, drug-, stress-induced) via NAc shell and CeA

- Clinical
  - ↓ Opioid craving by ~40% with liraglutide in individuals with OUD (Freet, 2025)

Opioid Use Disorder and Overdose

Early Preclinical	Late Preclinical	Phase I Clinical Trials	Phase II Clinical Trials	Phase III Clinical Trials	New Formulation
▪ NTR1 modulator ▪ 5HT2R agonist ▪ HBS087/HBS093 ▪ PN6041/PN6047 ▪ D-CYSee ▪ SBI-0801315/SBI-0799220 ▪ Opioid biased agonist ▪ MOR Selective agonist ▪ Oxy/Fentanyl nano-vaccine ▪ Fentanyl/heroin vaccine ▪ GDNF gene therapy	▪ BTRX-246040 ▪ PF5190457 ▪ AT-121 ▪ TRN-228 ▪ NaV1.8 inhibitor ▪ CS-1103 ▪ Methocinnamox ▪ Mitragynine analogs ▪ R-methadone prodrug ▪ MOR modulator ▪ GM-3009 (Oxa-iboga analog) ▪ SBS-226 ▪ M-KLH (Heroin Vaccine) ▪ Fentanyl vaccine ▪ mAb Fentanyl	▪ Lofexidine ▪ Lofexidine ▪ Dextromethorphan /Bupropion ▪ CVL-354 ▪ INDV-2000 ▪ AZD4041 ▪ KNX100 ▪ NYX-783 ▪ EC5026 ▪ SBS-1000 ▪ Kindolor ▪ Psilocybin ▪ MEB-1170 ▪ NRS-033 ▪ ITI-333 ▪ EPD2520 ▪ Oxycodone vaccine	▪ Cannabidiol ▪ Guanfacine ▪ Pregabalin + Lofexidine ▪ Suvorexant ▪ Pramipexole ▪ Olanzapine ▪ Ketamine ▪ Ketamine ▪ Ketamine ▪ Semaglutide ▪ Semaglutide ▪ Buprenorphine + Naltrexone ▪ Buprenorphine ▪ Buprenorphine ▪ INDV-2000 ▪ CSX-1004 (P1A4 Fentanyl mAb)	▪ Suvorexant	▪ Naltrexone 2-month injection ▪ BICX104 Naltrexone 3-month implant

UG3DA050325

PI: Sue Grigson

Pennsylvania State U. Hershey Medical Ctr

Semaglutide or placebo every week for 12 weeks

N=200

Reduce illicit opioid use in adults in outpatient treatment for opioid use disorder, and who are receiving either buprenorphine or methadone maintenance treatment.

Starting at a dose of 0.25 mg SC and advanced on a fixed-flexible dose schedule, based on tolerability, to a dose of 1.0 mg SC per week, or the maximum tolerated dose if less than 1.0 mg.

NCT06548490

Opioid Use Disorder and Overdose

Early Preclinical	Late Preclinical	Phase I Clinical Trials	Phase II Clinical Trials	Phase III Clinical Trials	New Formulation
▪ NTR1 modulator ▪ 5HT2R agonist ▪ HBS087/HBS093 ▪ PN6041/PN6047 ▪ D-CYSee ▪ SBI-0801315/SBI-0799220 ▪ Opioid biased agonist ▪ MOR Selective agonist ▪ Oxy/Fentanyl nano-vaccine ▪ Fentanyl/heroin vaccine ▪ GDNF gene therapy	▪ BTRX-246040 ▪ PF5190457 ▪ AT-121 ▪ TRN-228 ▪ NaV1.8 inhibitor ▪ CS-1103 ▪ Methocinnamox ▪ Mitragynine analogs ▪ R-methadone prodrug ▪ MOR modulator ▪ GM-3009 (Oxa-iboga analog) ▪ SBS-226 ▪ M-KLH (Heroin Vaccine) ▪ Fentanyl vaccine ▪ mAb Fentanyl	▪ Lofexidine ▪ Lofexidine ▪ Dextromethorphan /Bupropion ▪ CVL-354 ▪ INDV-2000 ▪ AZD4041 ▪ KNX100 ▪ NYX-783 ▪ EC5026 ▪ SBS-1000 ▪ Kindolor ▪ Psilocybin ▪ MEB-1170 ▪ NRS-033 ▪ ITI-333 ▪ EPD2520 ▪ Oxycodone vaccine	▪ Cannabidiol ▪ Guanfacine ▪ Pregabalin + Lofexidine ▪ Suvorexant ▪ Pramipexole ▪ Olanzapine ▪ Ketamine ▪ Ketamine ▪ Ketamine ▪ Semaglutide ▪ Semaglutide ▪ Buprenorphine + Naltrexone ▪ Buprenorphine ▪ Buprenorphine ▪ INDV-2000 ▪ CSX-1004 (P1A4 Fentanyl mAb)	▪ Suvorexant	▪ Naltrexone 2-month injection ▪ BICX104 Naltrexone 3-

R21DA060304

PI: Joji Suzuki
Brigham and Women's Hospital

12-week, double-blind, placebo-controlled, randomized trial of individuals with OUD newly initiating buprenorphine

Semaglutide weekly injections (n=23) or matching placebo (n=23).

Effects on cue-reactivity and preliminary efficacy, safety, and tolerability

NCT06639464

Stimulant Use Disorder

- Preclinical
  - ↓ Cocaine-induced hyperlocomotion, DA overflow, and reinstatement behavior via NAc shell and lateral septum
  - Exendin-4 / liraglutide reduced: methamphetamine self-administration, conditioned place preference, relapse/reinstatement behavior

- Clinical
  - Cocaine: no reduction in self-administration, euphoria, or craving after a single low-dose exenatide in CUD patients (RCT). The study is limited by acute dosing (n=3) (Yammine, 2023).
  - Methamphetamine: no published data. Results presented in ASCP on May 26, 2026.

Stimulant Use Disorder and Overdose

Early Preclinical	Late Preclinical	Clinical Trials	
		Phase I	
▪ SBI-0801315/SBI-0799220 ▪ SBS-518	▪ OMS 182399 ▪ PPL-138 ▪ NHB 1109 ▪ CocH5-Fc(M6)	▪ CS-1103 ▪ Exenatide ▪ BICX104/Bupropion ▪ STP-7-Mavoglurant ▪ Troriluzole ▪ Pentoxifylline ▪ Psilocybin ▪ Semaglutide	▪ S ▪

Compare 14 weeks of once-weekly semaglutide versus placebo, as an adjunct to CBT, (N=75)
Explore off-target effects on alcohol, tobacco and marijuana consumption
Semaglutide's titration schedule from 0.25 mg/week to 1 mg/week to explore treatment effects at each level, toward identifying a minimal effective dose

Results may support a fully-powered efficacy trial,

PI: Luba Yammine
R01 DA062720

Stimulant Use Disorder and Overdose

Early Preclinical	Late Preclinical	Clinical Trials	
		Phase I	Phase II
▪ SBI-0801315/SBI-0799220 ▪ SBS-518	▪ OMS 182399 ▪ PPL-138 ▪ NHB 1109 ▪ CocH5-Fc(M6)	▪ CS-1103 ▪ Exenatide ▪ BICX104/Bupropion ▪ STP-7-Mavoglurant ▪ Troriluzole ▪ Pentoxifylline ▪ Psilocybin ▪ Semaglutide	▪ Semaglutide ▪ Bupropion/Nalt

Two-phase study

1) Open-label single-arm Phase IIa trial of semaglutide for MeUD. To continue, therapy meet prespecified levels, and there is evidence of reduced methamphetamine use
2) Phase IIb placebo-controlled randomized trial of semaglutide versus placebo to determine the efficacy of this medication in achieving a clinically-meaningful reduction in methamphetamine use.

These studies will be done under FDA IND, in order to allow for potential future studies that could lead to a new indication for semaglutide as the first medication approved for MeUD.

PI: Phillip Coffin
UG3 DA063329

Cannabis Use Disorder

Early Preclinical	Late Preclinical	Clinical Trials		
		Phase I	Phase II	Phase III
		▪ Selonabant	▪ Cannabidiol/Hemp-derived cannabinoids	

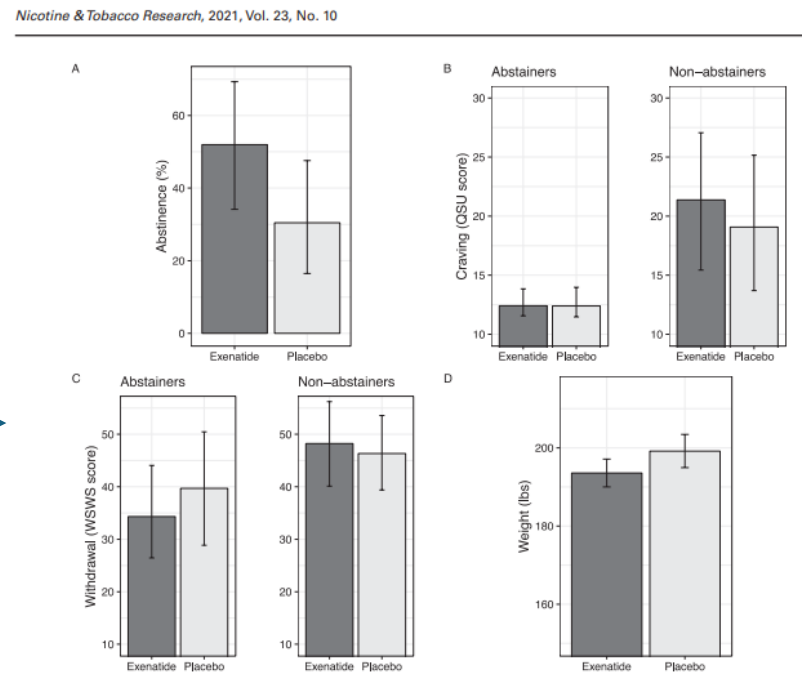
Tirzepatide

n=100
Weekly SC 24 weeks.
Initiated at 2.5 mg for 4 weeks (4 injections) and increased in 2.5 mg increments every 4 weeks as tolerated, up to a maximum dose of 15 mg

PI: Jia Bei Wang
NIDA IAA
NCT07468552

Nicotine Use Disorder

- Preclinical
  - Reduces nicotine reward
  - ↓ Self-administration, cue-reactivity, hyperlocomotion
  - ↓ extracellular DA in NA
- Clinical
  - GLP-1RAs reduced post-cessation weight gain, potentially supporting smoking cessation.
  - Exenatide, in combination with the NRT improved smoking abstinence, reduced craving and withdrawal symptoms, and decreased weight gain among abstainers (Yammine, 2021)
  - Potential synergy with varenicline/NRT



Tobacco Use Disorder

Early Preclinical	Late Preclinical	Clinical Trials	
		Phase I	Phase II
	▪ ATI-1013 (anti-nicotine monoclonal antibody)	▪ AT-1082 (α3β4 partial agonist) ▪ Tetrahydrocannabivarin ▪ mGlu2 PAM SBP-9330	▪ Exenatide + NRT ▪ Tirzepatide+NRT

R01DA053241

PI: Luba Yammine
University of Texas Health Science Center, Houston

To determine if exenatide improves end-of-treatment smoking abstinence rates and to determine if exenatide mitigates post-cessation weight gain.

Treatment seeking (n=216)

NCT05610800

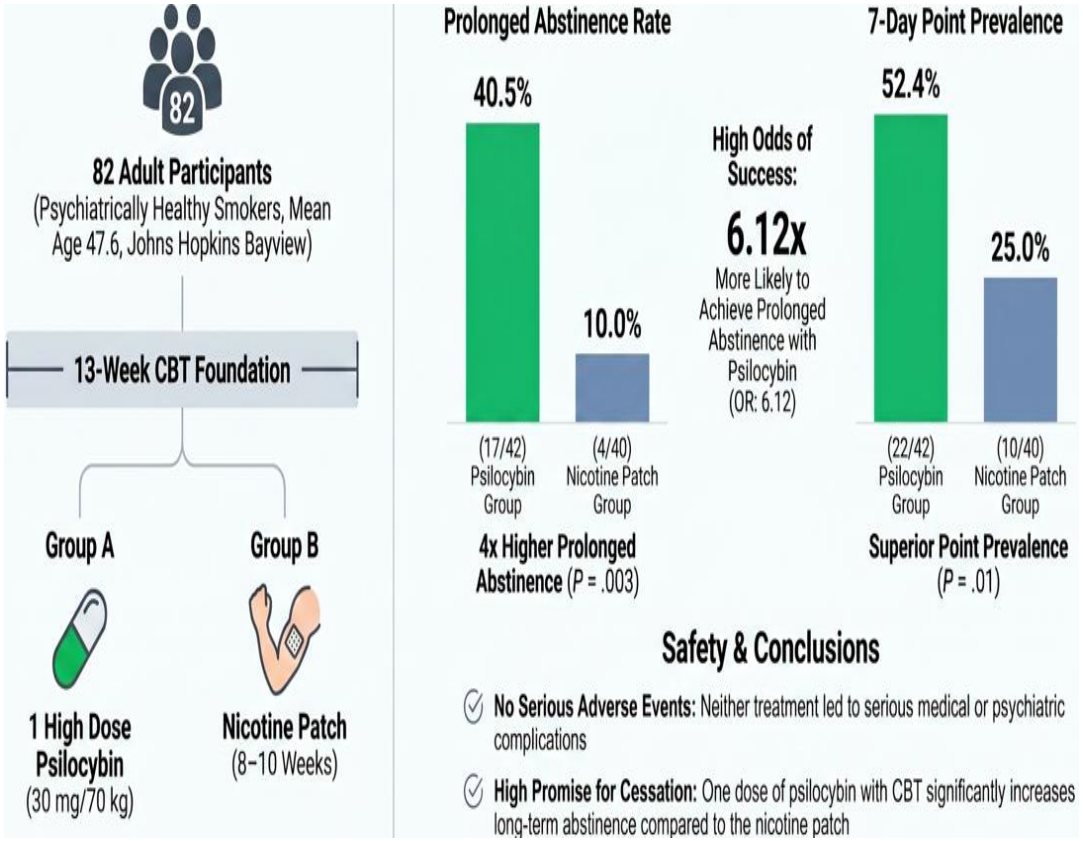
Tobacco Use Disorder

Early Preclinical	Late Preclinical	Clinical Trials	
		Phase I	Phase II
	▪ ATI-1013 (anti-nicotine monoclonal antibody)	▪ AT-1082 (α3β4 partial agonist) ▪ Tetrahydrocannabivarin ▪ mGlu2 PAM SBP-9330	▪ Exenatide + NRT ▪ Tirzepatide+NRT

Multi-site, 24-week trial
Outcomes (e.g., cigarettes per day, post-cessation weight gain, cardiovascular risk factors) in treatment-seeking people who smoke.
Inform dose for pivotal Phase III clinical trials.

U01DA064384
PI: Christian Hendershot
University of Southern California, Los Angeles.

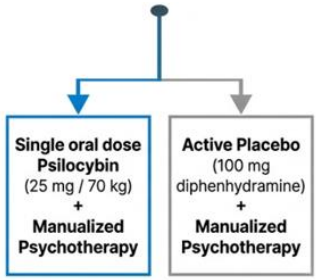
RCT of Psilocybin vs. Nicotine Patch for Smoking Cessation



Psilocybin abstinence rates higher than for typical treatments, suggesting promise for tobacco cessation.

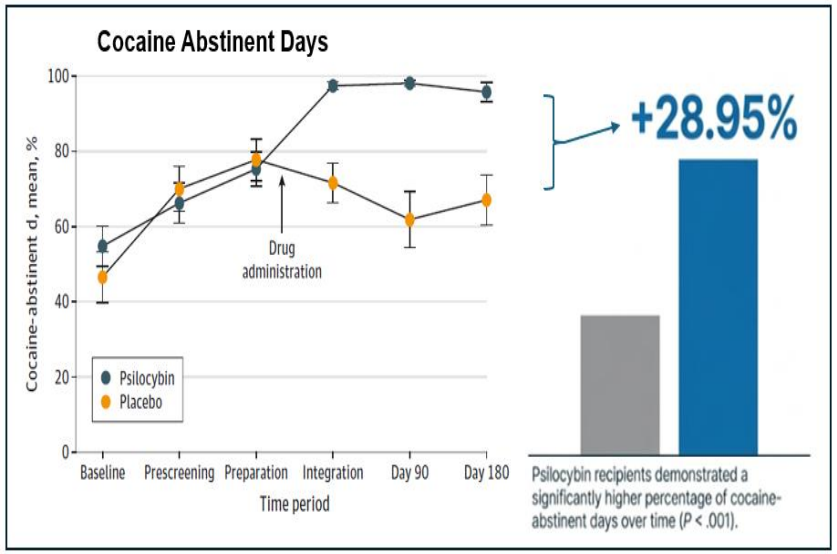
Johnson et al. JAMA Netw Open. 2026

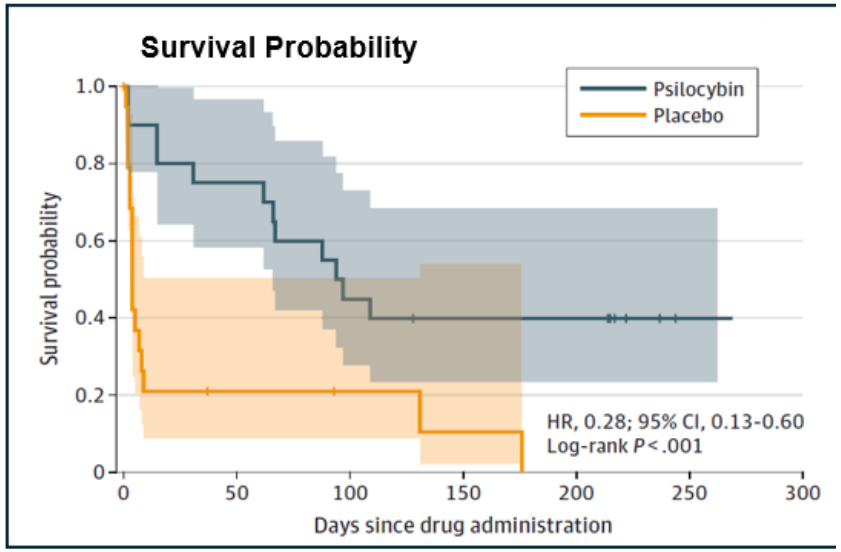
RCT of Psilocybin for Treatment of Cocaine Use Disorder: RCT



No Serious Adverse Events

- No rescue medications administered.
- All expected adverse events (primarily occurring during the all-day drug session) resolved completely with no sequelae.

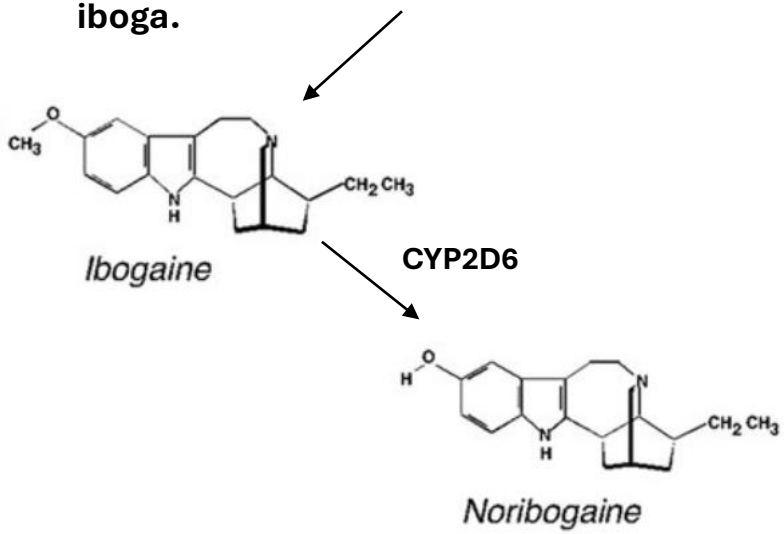




Hendricks et al. Jama Network Open 2026

Ibogaine: Potential Therapeutic Applications

Naturally occurring psychoactive compound found in the root bark of the African shrub Tabernanthe iboga.



- Consistent but uncontrolled evidence that a single-session ibogaine (noribogaine) reduces opioid and other drug withdrawal symptoms and craving.
- Cardiac toxicity: ibogaine and noribogaine prolong QT via hERG blockade that can lead to ventricular arrhythmias and death.
- Research Goals
  - Reduce cardiotoxicity risks
  - Safer compounds that retain anti-addictive properties.
  - Reduce hallucinogenic effects

Köck et al. J Subst Abuse Treat.138:108717 (2022)

Opioid Use Disorder and Overdose

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- UG3: GMP-manufacturing and formulation
- IND-enabling toxicity studies
- Therapeutic exposures and target engagement
- UH3: first-in-human trials
- Support subsequent Phase 2

UG3DA06005
PI: Gerard Mareck
Gilgamesh

https://nida.nih.gov/about-nida/organization/divisions/division-therapeutics-medical-consequences-dtmc

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)

National Institutes of Health (NIH)

Components of Participating Organizations

National Institute on Drug Abuse (NIDA)

Funding Opportunity Title

Development of Interventions to Prevent and Treat Substance Use Disorders and Overdose (UG3/UH3 - Clinical Trial Optional)

Act

Application Due Dates			Review and Award Cycles		
New	**Renewal / Resubmission / Revision (as allowed)**	**AIDS - New/Renewal/Resubmission/Revision, as allowed**	**Scientific Merit Review**	**Advisory Council Review**	**Earliest Start Date**
October 20, 2025	November 20, 2025	December 22, 2025	March 2026	May 2026	July 2026
February 20, 2026	March 20, 2026	April 20, 2026	July 2026	October 2026	December 2026
June 22, 2026	July 20, 2026	Not Applicable	November 2026	January 2027	April 2027
October 20, 2026	November 20, 2026	Not Applicable	March 2027	May 2027	July 2027
February 22, 2027	March 22, 2027	Not Applicable	July 2027	October 2027	December 2027
June 21, 2027	July 20, 2027	Not Applicable	November 2027	January 2028	April 2028
October 20, 2027	November 22, 2027	Not Applicable	March 2028	May 2028	July 2028
February 22, 2028	March 20, 2028	Not Applicable	July 2028	October 2028	December 2028
June 20, 2028	July 20, 2028	Not Applicable	November 2028	January 2029	April 2029