

# A MOSAIC PERSPECTIVE OF THE PSYCHEDELICS LANDSCAPE

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# **DISCLAIMER**

- THIS PRESENTATION REFLECTS THE VIEWS OF THE AUTHOR AND SHOULD NOT BE CONSTRUED TO REPRESENT FDA'S VIEWS OR POLICIES.

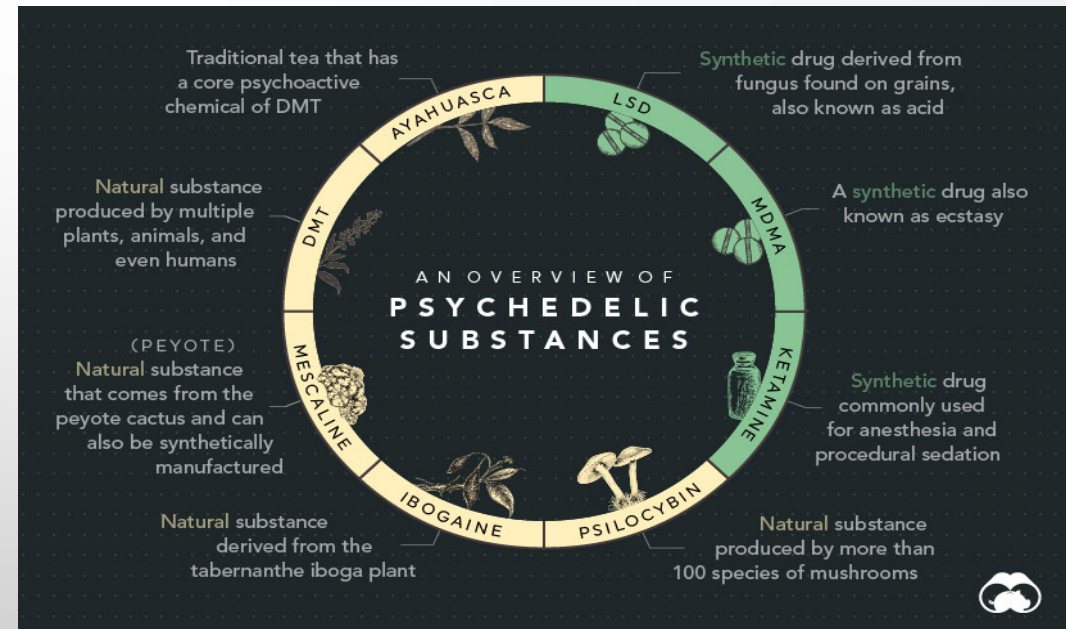
# OUTLINE

- BACKGROUND
- RESEARCH OVERVIEW
- BEYOND DRUG DEVELOPMENT – POLICY  
IMPLICATIONS OF THE PSYCHEDELICS RESURGENCE



# COMMONLY STUDIED PSYCHEDELIC SUBSTANCES

- HALLUCINOGENS ARE A DIVERSE GROUP OF SUBSTANCES THAT CAN ALTER A PERSON'S CONSCIOUSNESS AND COGNITIVE PROCESS
- THEY FALL INTO TWO BROAD GROUPS:
  1. "CLASSIC" HALLUCINOGENS – WHICH INCLUDE LSD, PSILOCYBIN, IBOGAINE
  2. DISSOCIATIVE TYPES – WHICH CAN INCLUDE PCP, KETAMINE



1. Hallucinogens Drug Facts – NIH/NIDA . <https://nida.nih.gov/publications/drugfacts/hallucinogens>

2. Image credit: 3. Image credit - Visual Capitalist: The History of Psychedelics: <https://www.visualcapitalist.com/the-history-of-psychedelics-part-1-of-2/>

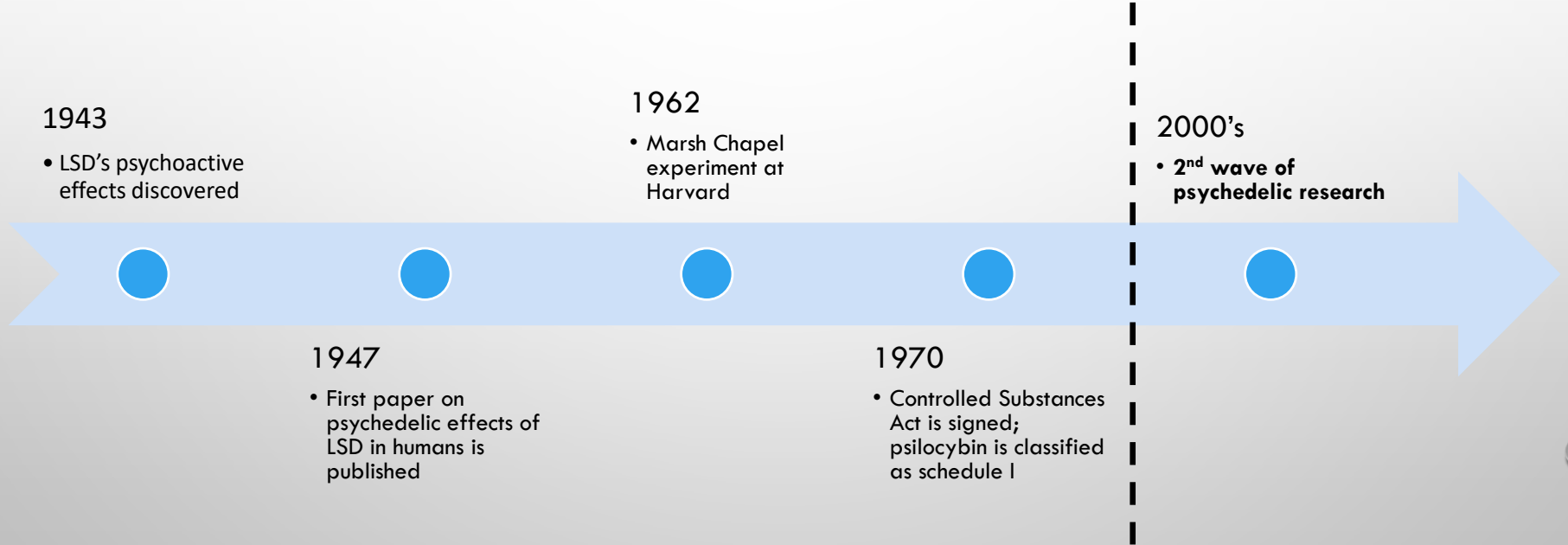
# BRIEF HISTORY – HUMAN’S QUEST FOR MIND-ALTERING EXPERIENCE FROM PLANTS

- PSYCHEDELICS HAVE FLOURISHED FOR THOUSANDS OF YEARS IN INDIGENOUS CULTURES<sup>1</sup>
- HUMANITY’S QUEST FOR PSYCHOACTIVE MIND-ALTERING PLANTS IS EVIDENCED IN ARCHAEOLOGICAL WRITINGS<sup>2</sup>
- WESTERN/EUROPEAN EXPLORATORY ‘RESEARCH’ BEGAN IN THE LATE NINETEENTH TO EARLY TWENTIETH CENTURY WITH THE IDENTIFICATION OF MESCALINE IN PEYOTE CACTUS PLANTS<sup>3</sup>
- MODERN PSYCHEDELIC RESEARCH BEGAN IN 1938 WITH THE WORK OF ALBERT HOFFMAN<sup>4</sup>

## Sources:

1. Ethical and legal issues in psychedelic harm reduction and integration xxxxxx <https://harmreductionjournal.biomedcentral.com/articles/10.1186/s12954-021-00489-1>
2. Samorini, Georgio (2019). Journal of Psychedelics Studies. Vol 3, issue2. The oldest archaeological data evidencing the relationship between homo sapiens and psychoactive plants: A worldwide overview. <https://akjournals.com/view/journals/2054/3/2/article-p63.xml>
3. Bruhn JG, et. al. (2002). . Mescaline use for 5700 years. Lancet. 359(9320):1866.
4. Doblin, R.E., et. al. (2019). The Past and future of psychedelics science: A introduction to this issue. In Psychoactive drugs, 4 (51), 2. <https://pubmed.ncbi.nlm.nih.gov/31132970/#:~:text=Modern%20psychedelic%20research%20began%20when,they%20would%20set%20in%20motion.>

# SELECT NOTABLE MILESTONES IN PSYCHEDELICS RESEARCH AND DEVELOPMENT



Sources: 1. Carhart-Harris, R. and Goodwin, G.M (2017) Neuropsychopharmacology, Oct. 42, 2005 – 2013

# EPI SNAPSHOT: PAST-YEAR USE, 2020 NSDUH

- IN 2020, 2.6% OF PEOPLE AGED 12+ (OR 7.1M PEOPLE) USED HALLUCINOGENS IN THE PAST YEAR
- 1.4M PEOPLE INITIATED HALLUCINOGEN USE IN THE PAST YEAR, INCLUDING 251,000 ADOLESCENTS

Figure 9. Past Year Illicit Drug Use: Among People Aged 12 or Older; 2020

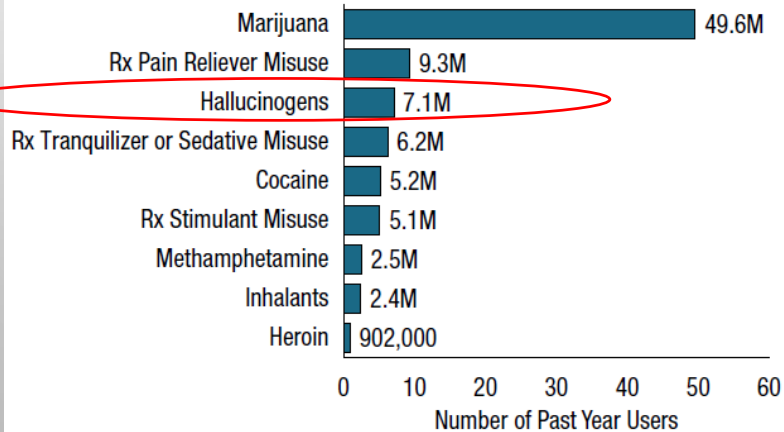
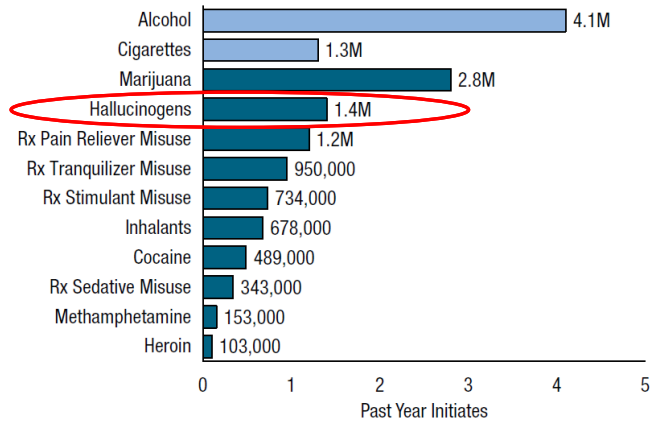


Figure 21. Past Year Initiates of Substances: Among People Aged 12 or Older; 2020



2020 NSDUH Annual National Report | CBHSQ Data ([samhsa.gov](https://www.samhsa.gov))

Note: category of hallucinogens includes LSD, PCP, peyote, mescaline, psilocybin, MDMA, ketamine, DMT and Salvia divinorum

## SUMMARY OF KEY RECENT TRENDS IN PSYCHEDELICS USE

|   | Data Source(s), Age group, Years   | MDMA                        | Psilocybin                | LSD                   |
|---|--|-----------------------------|---------------------------|-----------------------|
| <b>Past-year Nonmedical Use, Young Adults: Prevalence and Trend</b>       | NSDUH, 18-25 years, 2015-2020;<br>MTF, 12 <sup>th</sup> graders, 2015-2019 | ~3%, declining trend        | ~2%, flat trend           | ~3%, increasing trend |
| <b>Past-year Nonmedical Use, General Population: Prevalence and Trend</b> | NSDUH, 12 years and older, 2015-2020                                       | ~1%, slight declining trend | <i>Data not available</i> | ~1%, increasing trend |

NSDUH: Substance Abuse and Mental Health Services Administration (SAMHSA)'s public online data analysis system (PDAS) Survey: National Survey on Drug Use and Health (NSDUH). Available at <https://pdas.samhsa.gov>

MTF: Monitoring the Future (MTF) National Survey Results on Drug Use Volume I, Secondary school students. Available at <http://monitoringthefuture.org/pubs.html#monographs>

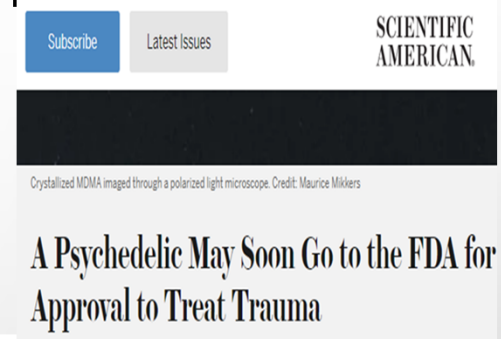


The background of the slide is a light gray gradient. It is decorated with several realistic water droplets of various sizes and shapes, scattered across the top and bottom edges. The droplets have highlights and shadows, giving them a three-dimensional appearance.

# **RESEARCH OVERVIEW**

# DRUG DEVELOPMENT SNAPSHOT

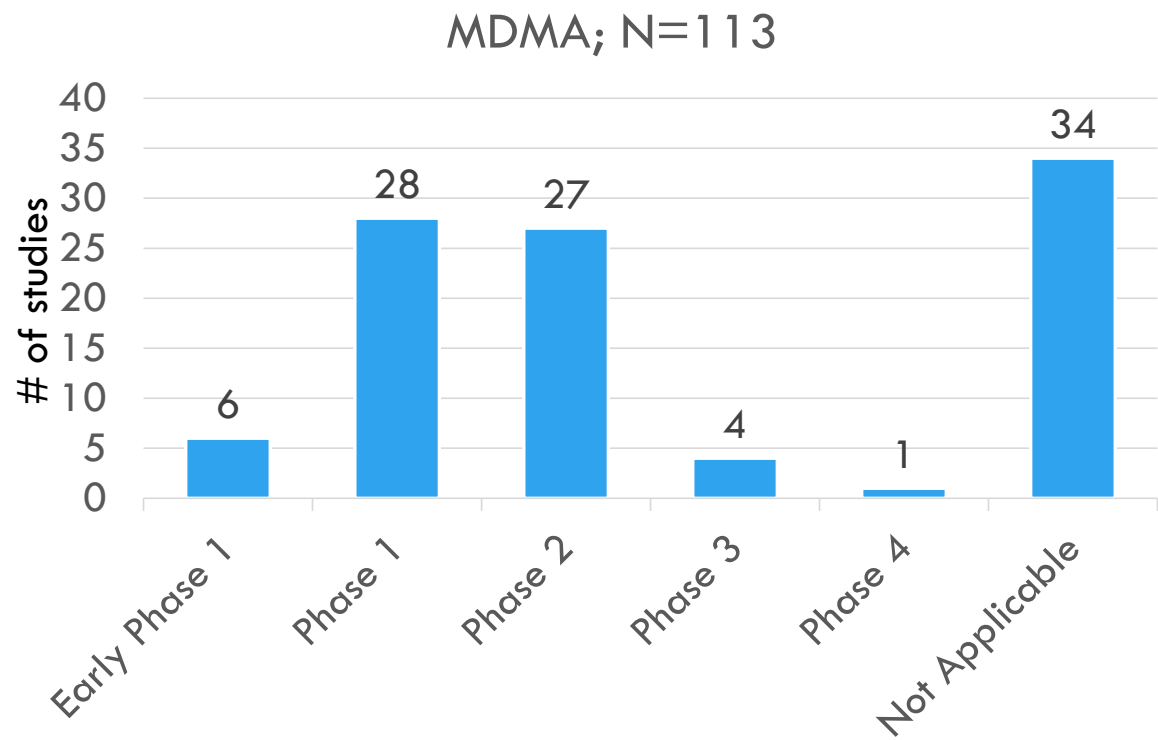
- 113 CLINICAL TRIALS FOR MDMA
- 99 CLINICAL TRIALS FOR PSILOCYBIN
- 29 CLINICAL TRIALS FOR LYSERGIC ACID DIETHYLAMIDE (LSD)



Source: Clinicaltrials.gov, Accessed 2/16/22; 5/16/22

1. Carhart- Harris, et al (2021). Trial of psilocybin versus escitalopram for depression. *New England Journal of Med.*; **384**: 1402-1411
  2. Mitchell JM, et. al. (2021). MDMA-assisted therapy for severe PTSD: a randomized, double-blind, placebo-controlled phase 3 study. In *Nature Med.* ; **27**: 1025-1033
- Images: <https://fortune.com/2022/01/26/fda-clears-bsd-based-drug-clinical-trials/>; <https://www.livescience.com/psilocybin-depression-breakthrough-therapy.html>;

# MDMA TRIALS: CLINICAL DEVELOPMENT

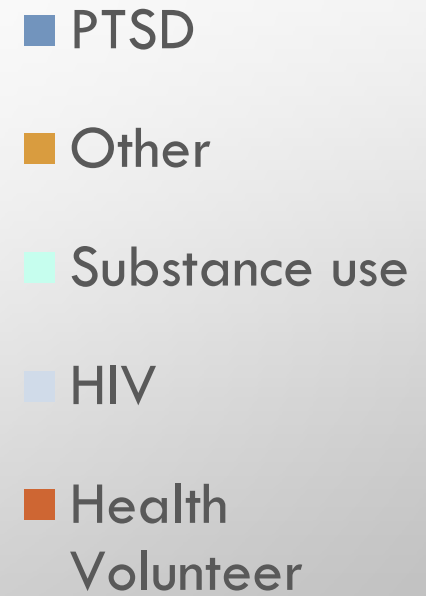
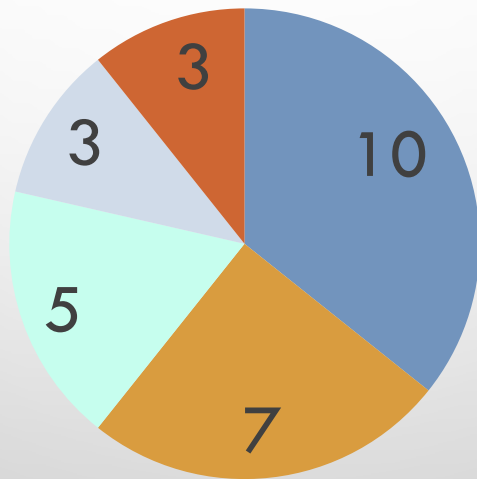


Source: Clinicaltrials.gov, Accessed 5/16/22

# MDMA CLINICAL TRIALS: TREATMENT INDICATIONS

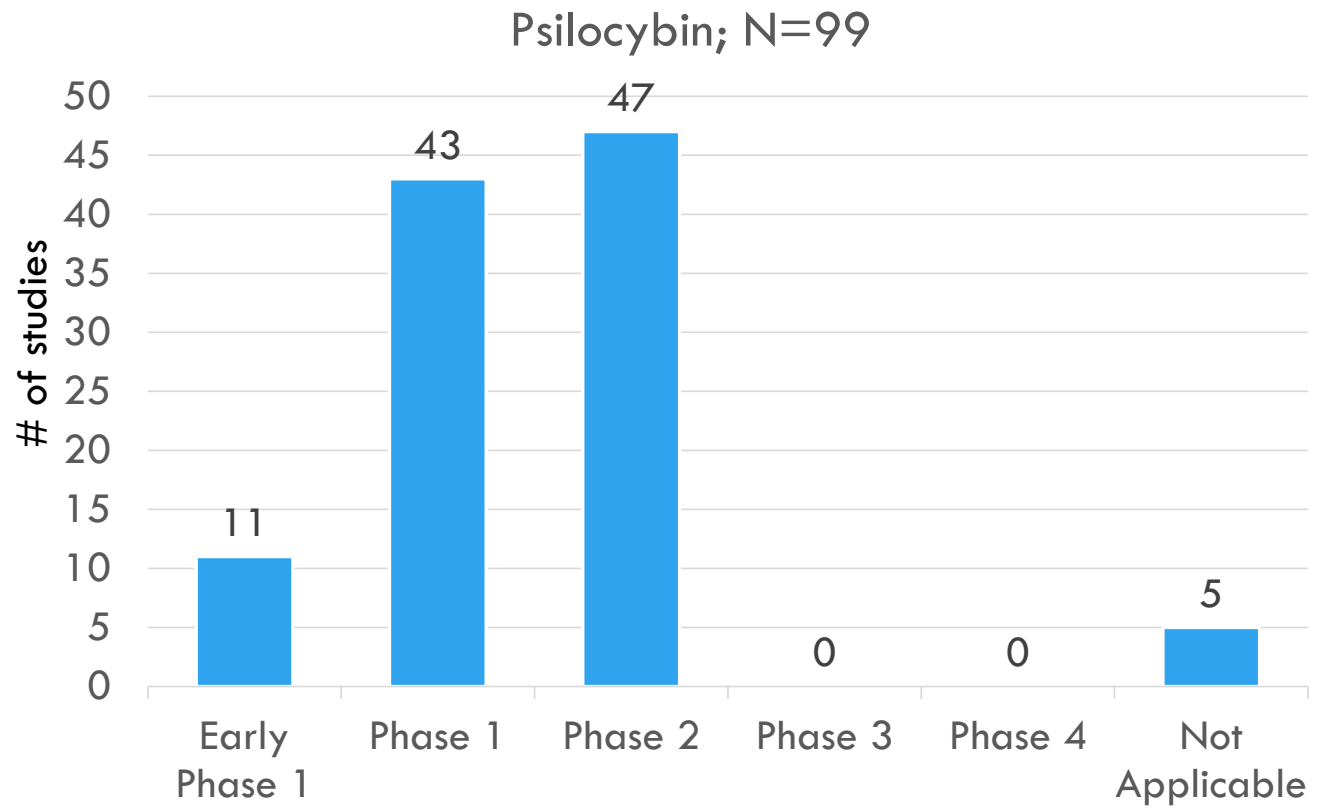
Partial list of indications studied from [clinicaltrials.gov](https://clinicaltrials.gov). Includes “active”, “recruiting”, and “enrolling” studies.

N=28



- Other includes - Depression, interpersonal interaction, and diabetes, among others

# PSILOCYBIN TRIALS: CLINICAL DEVELOPMENT

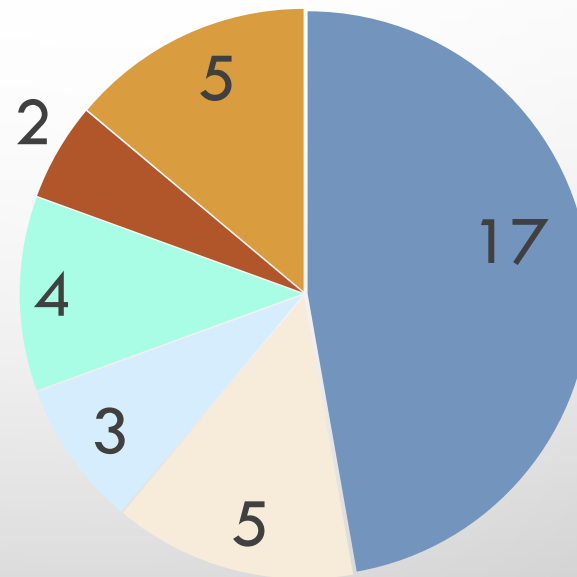


Source: Clinicaltrials.gov, Accessed 5/16/22

# PSILOCYBIN CLINICAL TRIALS: TREATMENT INDICATIONS

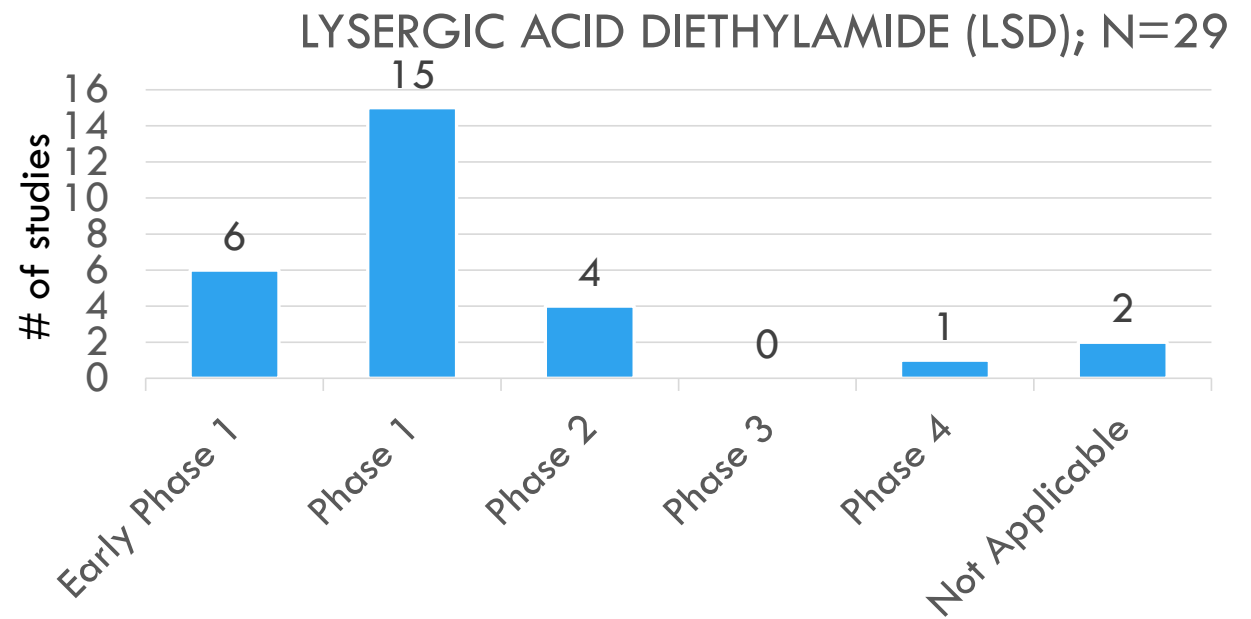
Partial list from  
clinicaltrials.gov.  
Includes studies  
described as “active”,  
“recruiting”, and  
“enrolling”, based on  
date of extraction

N=36



- Other includes - Opioid use, nicotine dependence, and healthy volunteers, among others

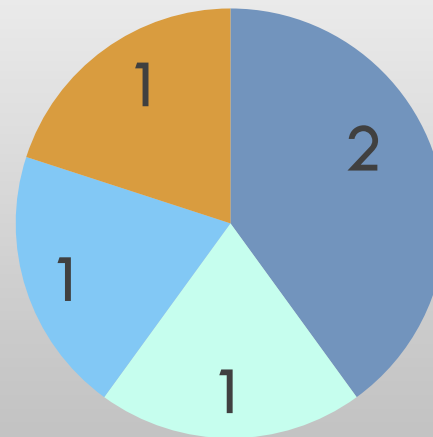
# LSD TRIALS: CLINICAL DEVELOPMENT



Source: Clinicaltrials.gov, Accessed 5/16/22

# LSD CLINICAL TRIALS: TREATMENT INDICATIONS

Partial list from  
clinicaltrials.gov.  
Includes studies  
described as “active”,  
“recruiting”, and  
“enrolling”, based on  
date of extraction;



- Healthy Volunteer
- Headache
- Depression
- Substance Use



# DRUG DEVELOPMENT SNAPSHOT: BREAKTHROUGH THERAPY

| Year Granted | Sponsor   | Drug                 | Indication                            |
|--------------|---|----------------------|---------------------------------------|
| 2017         | Multidisciplinary Association of Psychedelic Studies (MAPS) | MDMA                 | Post-traumatic stress disorder (PTSD) |
| 2018         | COMPASS Pathfinder Limited                                  | Psilocybin (COMP360) | Treatment-resistant depression (TRD)  |
| 2019         | Usona Institute   | Psilocybin           | Major depressive disorder (MDD)       |

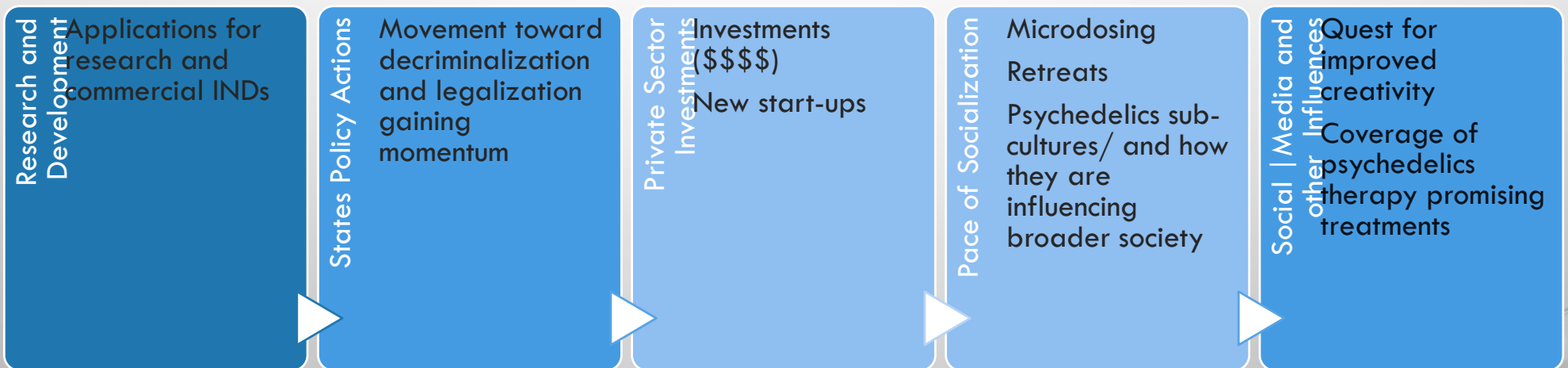
Sources:

MDMA breakthrough status: <https://maps.org/news/media/press-release-fda-grants-breakthrough-therapy-designation-for-mdma-assisted-psychotherapy-for-ptsd-agrees-on-special-protocol-assessment-for-phase-3-trials/>; Psilocybin (COMPASS): <https://www.livescience.com/psilocybin-depression-breakthrough-therapy.html>; Psilocybin (Usona Institute): <https://www.businesswire.com/news/home/20191122005452/en/FDA-grants-Breakthrough-Therapy-Designation-to-Usona-Institutes-psilocybin-program-for-major-depressive-disorder>

# **BEYOND DRUG DEVELOPMENT**

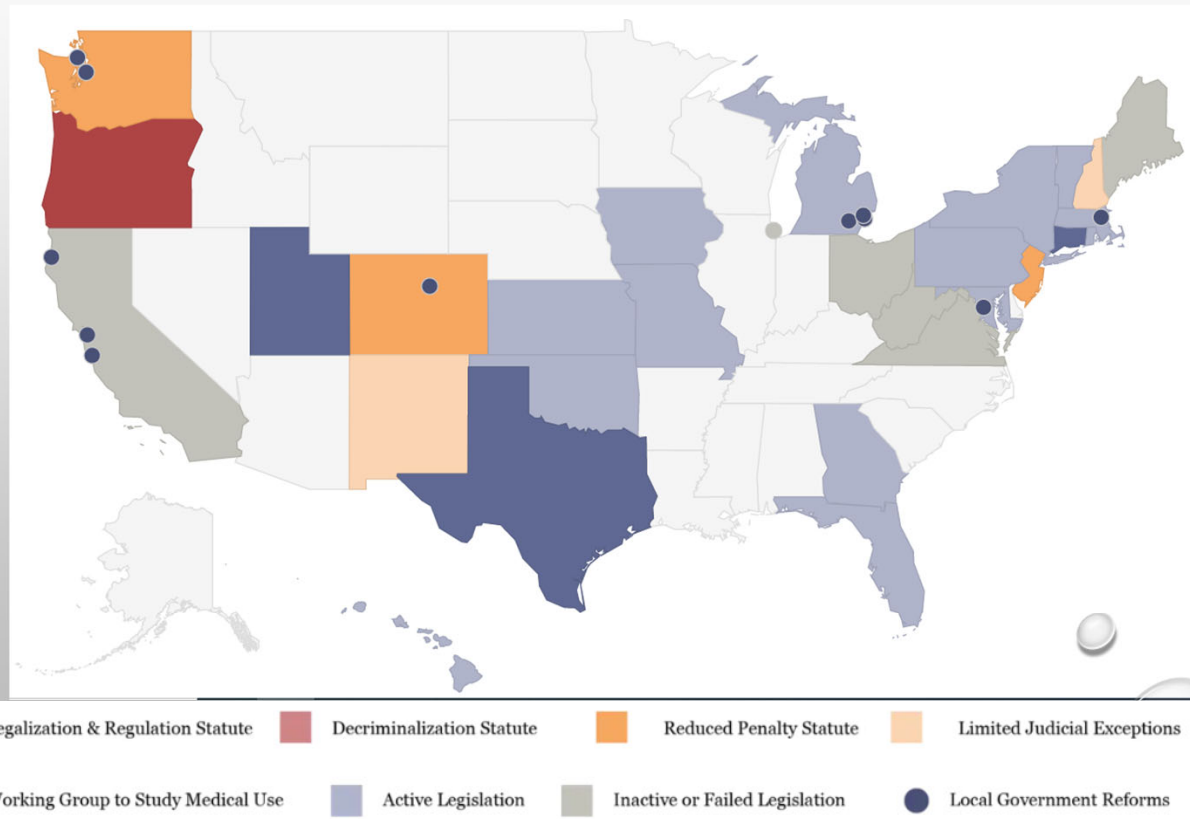
POLICY IMPLICATIONS OF THE  
PSYCHEDELICS RESURGENCE

# SOCIAL AND ENVIRONMENTAL DRIVERS OF RENEWED INTERESTS



# MAPPING POLICY REFORMS ACROSS STATES

- LEGALIZATION AND DECRIMINALIZATION STATUTES – OREGON
- ACTIVE LEGISLATION – 14 STATES (MA., NY, VT, PA., MD., MI., IA., MS., KS., OK., GA., FL., HI., UT.)
- INACTIVE OR FAILED LEGISLATION - 5 STATES (CA., MN., OH., WV., AND VA.)
- REDUCED PENALTY - 3 STATES (CO., NJ., WA)
- LIMITED JUDICIAL EXCEPTIONS – (NH).
- WORKING GROUP TO STUDY PSYCHEDELICS – ONE STATE (TX) + 10 MUNICIPALITIES (INCLUDING SEATTLE, DENVER, DETROIT, AND SANTA CRUZ, ARCATA, AND OAKLAND – IN CA.)



## RECENT STATE ACTIONS FOCUSED ON EXEMPTIONS RELATED TO HEALTH, SOCIAL JUSTICE/EQUITY, AND COGNITIVE LIBERTY JUSTIFICATIONS

- **CONNECTICUT & TEXAS (2021):** LAWS REQUIRING STUDIES ON MEDICAL USE OF PSYCHEDELICS. TEXAS' PROPOSAL PARTICULARLY HIGHLIGHTS ACCESS FOR VETERANS
- **CALIFORNIA ( CURRENTLY INACTIVE):** BILL WOULD LEGALIZE PERSONAL USE OF CERTAIN PSYCHEDELICS DEFEATED BUT PLANS TO REVISIT IN 2023 WITH POSSIBLE AMENDMENTS.
- **MISSOURI:** BILL WOULD EXPAND STATE'S RIGHT TO TRY LAW TO POSSIBLY INCLUDE PSYCHEDELICS (IBOGAINE, PSILOCYBIN, LSD)ACCESS FOR SERIOUS ILLNESSES
- **NEW YORK STATE'S BILL A08569** - COULD LEAD TO CREATION OF PSILOCYBIN TREATMENT CENTERS, WITH PRIORITY GIVEN TO WOMEN AND MINORITY OWNED AND ACCESS FOR VETERANS.

# PSYCHEDELICS IN THE NEWS

## Public Sector Influence (research funding)

HOME > CULTURE > CULTURE FEATURES NOVEMBER 11, 2021 10:47A

### U.S. Government Funds First Therapeutic Psilocybin Research in 50 Years

The National Institutes of Health is helping to fund a Johns Hopkins study looking at whether the psychoactive chemical could help people quit smoking

By **SHELBY HARTMAN & MADISON MARGOLIN**



Special Reports > Exclusives

### Academic Centers Start to Take Psychedelics Seriously

— "You're not sticking your neck out as much as you would 10 years ago," one director says

by **Ryan Basen**, Enterprise & Investigative Writer, MedPage Today November 24, 2021

### Grant Supports Development of Training for Psychiatrists in Psychedelic Medicine


March 10, 2022

## Private Sector Influence (drug /therapy development)

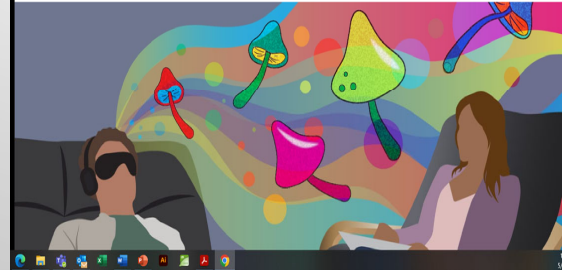
05-13-22 | 7:00 AM

### The next frontier of psychedelic therapy could be your couch

Ketamine therapy pioneer Field Trip is partnering with telehealth company Nue Life to bring psychedelic treatments into the home.



### A Long, Strange Trip: Psychedelics Meet Mainstream Medicine



## Socialization / Recreational

The New York Times

### The Rise of Psychedelic Retreats

Even with cause for concern, retreats in countries like Costa Rica and Jamaica, as well as in the United States, have been popping up for more than a decade.

### More People Are Microdosing for Mental Health. But Does It Work?

Scientists are split over whether the benefits some microdosers experience are a placebo effect or something more.

The New York Times



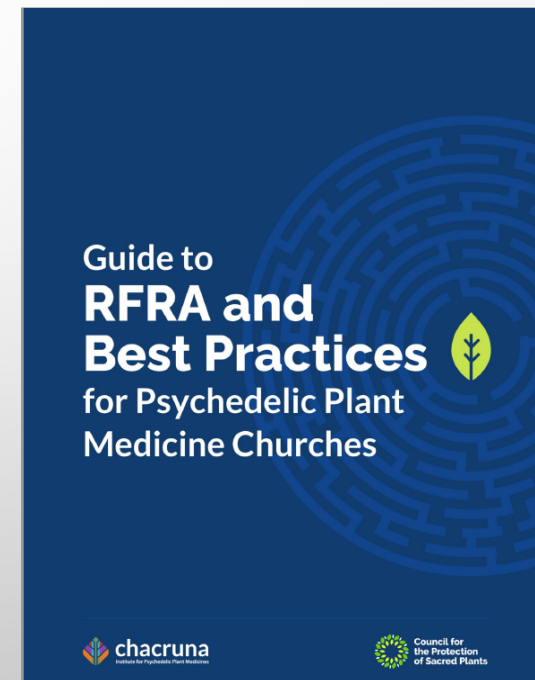
### PSYCHEDELIC-INDUCED CREATIVITY: FACT OR FICTION?

This post is also available in  Deutsch

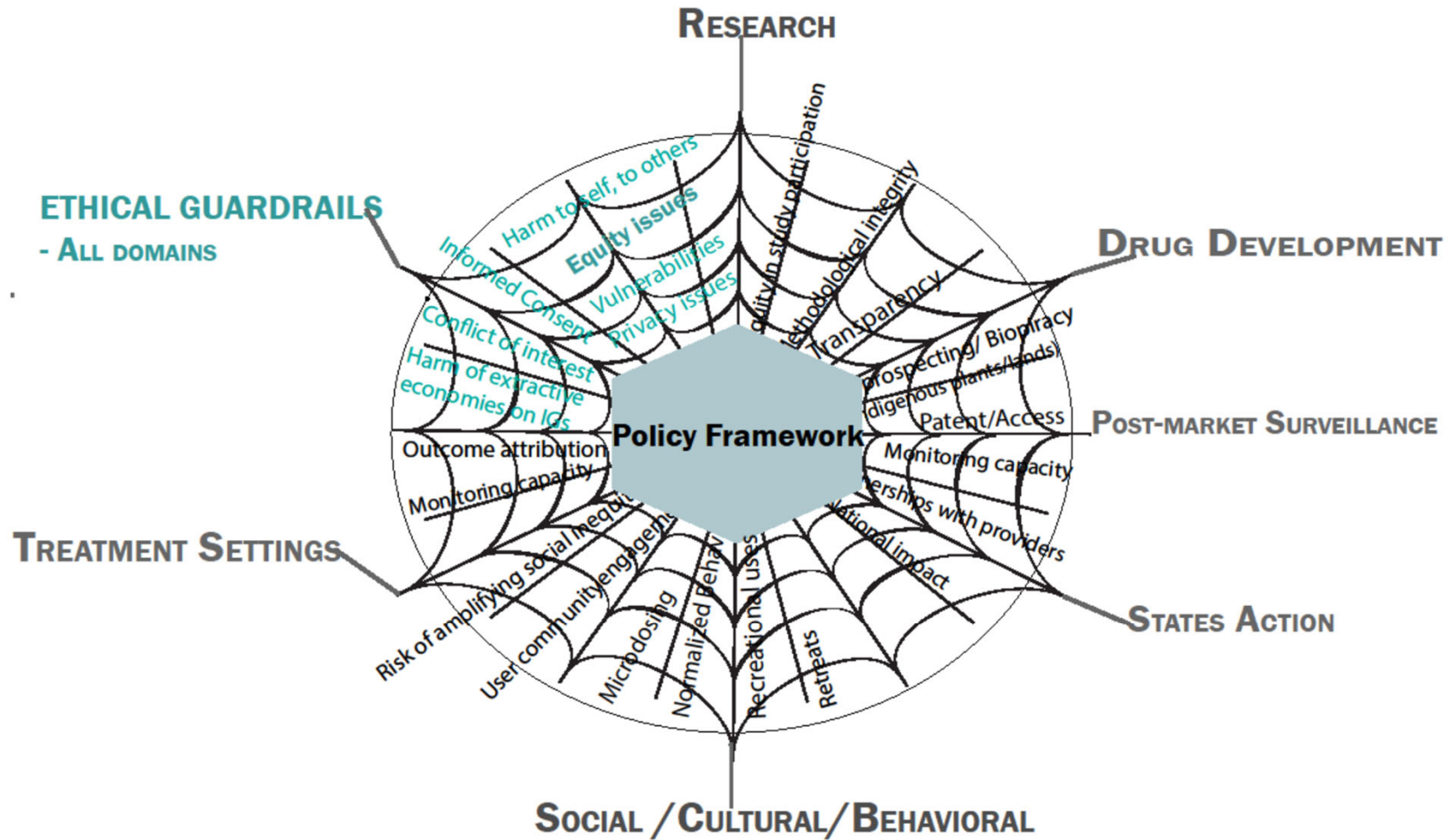


# RELIGIOUS FREEDOM RESTORATION ACT

- PROHIBITS FEDERAL GOVERNMENT FROM SUBSTANTIALLY BURDENING A PERSON'S EXERCISE OF RELIGION; DEA DISCRETION TO GRANT OR DENY ALL RELIGIOUS EXEMPTIONS
- USE OF THE SUBSTANCE MUST COMPLY WITH ALL OTHER REGULATIONS, INCLUDING THOSE AFFECTING SAFETY
- RECENTLY RELEASED BEST PRACTICES GUIDE FOR SPIRITUAL USE OF PSYCHEDELICS



# POLICY CONSIDERATIONS





# THANK YOU!

## **ACKNOWLEDGEMENT**

- CSP (VERONICA UZOEBO)
- OSE/DPV
- OND /DP/OMPI
- OMP