

Navigating Psychedelic Journeys: A Comprehensive Webinar on Psilocybin Therapy and the End-of-Life Experience



Host: José Pereira

Presenters: David Clements and Claudio Soares

Date: April 29, 2024

Territorial Honouring

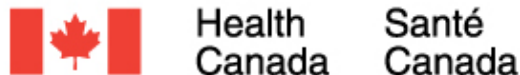


The Palliative Care ECHO Project

The Palliative Care ECHO Project is a 5-year national initiative to cultivate communities of practice and establish continuous professional development among health care providers across Canada who care for patients with life-limiting illness.

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The Palliative Care ECHO Project is supported by a financial contribution from Health Canada. The views expressed herein do not necessarily represent the views of Health Canada.



LEAP Core

- Interprofessional course that focuses on the essential competencies to provide a palliative care approach.
- Taught by local experts who are experienced palliative care clinicians and educators.
- Delivered online or in-person.
- Ideal for any health care professional (e.g., physician, nurse, pharmacist, social worker, etc.) who provides care for patients with life-threatening and progressive life-limiting illnesses.
- Accredited by CFPC and Royal College.



Learn more about the course and topics covered by visiting

www.pallium.ca/course/leap-core

Introductions

Host

Dr. José Pereira, MBChB, CCFP(PC), MSc, FCFP, PhD

Professor, Faculty of Medicine, University of Navarra, Spain.

Professor, Division of Palliative Care,
Department of Family Medicine, McMaster University, Hamilton, ON, Canada
Scientific Advisor and Co-Founder, Pallium Canada

Presenters

David Clements

Executive Director, Psychedelics Research
Queen's University

Claudio Soares, MD, PhD, FRCPC, MBA

Professor of Psychiatry, Queen's University
Regional Lead, Mental Health & Addictions, Ontario Health

Chair, Psychedelics Science Advisory Committee
Queen's University

Guest Panelists

Dr. Kylea Potvin, MD FRCPC

Medical Oncologist

London Regional Cancer Program

Associate Professor

Western University

Dr. Lyle Galloway

Medical Lead, Pain/Palliative Care, Tom Baker Cancer Centre, Calgary

Co-Lead, Alberta Provincial Palliative Team

Geneviève Lalumière, BScN, RN MN

Clinical Nurse Specialist and Coordinator

Regional Palliative Consultation Team

Elisabeth Bruyère Hospital

Conflict of Interest

Pallium Canada

- Non-profit.
- Partially funded through a contribution by Health Canada.
- Generates funds to support operations and R&D from course registration fees and sales of the Pallium Pocketbook.

Host/Presenters

- Jose Pereira: Scientific Advisor, Pallium Canada.
- David Clements: The Psychedelics Research Collaborative at Queen's has received donations from a number of private, philanthropic and professional associations since its launch in 2021.
- Claudio Soares: Dr. Soares has served as a consultant for Otsuka, Bayer, Eisai and Diamond Therapeutics and received grants from Ontario Brain Institute and CIHR.

Welcome and Reminders

- For comments, please use the chat function.
- For questions, please use the Q&A function, these questions will be addressed at the end of the session.
- This session is being recorded—this recording and slide deck will be emailed to registrants within the next week.
- Remember not to disclose any Personal Health Information (PHI) during the session.

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Renaissance to Revolution: Emerging Challenges for Policy and Practice

- Psychedelics are in increasing demand by patients, and a convergence of social trends is behind it
- Entrepreneurship abounds, but profit remains elusive (so far)
- Research continues to grow rapidly, but will continue to lag the needs of policymakers, providers, patients and the public.
- As the scientific evidence grows, so too will negative experiences
- The landscape for palliative care providers will continue to evolve rapidly



Renaissance Redux

- *Psychedelics remain illegal under the Controlled Drugs and Substances Act (Schedules 1 & 3)*
- *Access for research is through Clinical Trial Applications (CTA) or applications to Health Canada's Special Access Program.*
- *Since 2021, Section 56(1) criminal code exemptions are no longer being granted for palliative care (currently being challenged in the courts)*

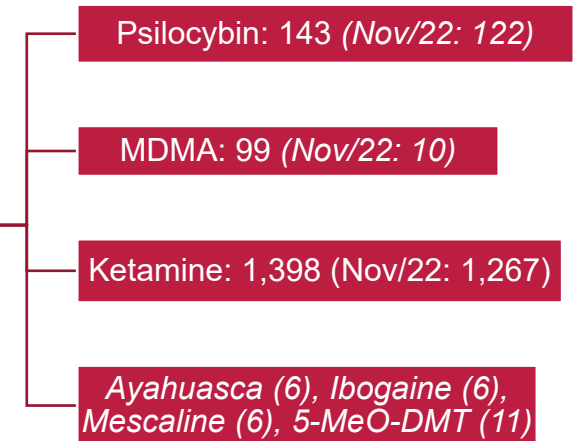
Since 2400 BCE (?)
Psychedelics used by Indigenous Peoples in the Americas, and parts of Africa.

1940s – 1970s
Research on psychedelics as “cognitive aids” and for conditions such as alcoholism (LSD)

1970s – 2000s: Prohibition
Research (and therapy) underground

2006 - 2020
“Research Renaissance”
(and the Pollan effect)

2020: The New Era
(including a growing number of registered trials (1))



Palliative Care at the Leading Edges



- Palliative care has been at the front lines of changes this decade (why?)
- Ongoing Section 7 challenges could result in courts providing direction to legislators (but this is a way off)
- Patients will expect providers to be experts in this area

You Say You Want a Revolution?

A risk-managed approval of MDMA by the FDA in the US is likely this year

New drug development is likely to lead to novel formulations of currently available drugs, as well as new delivery mechanisms (e.g. modified release dosage).

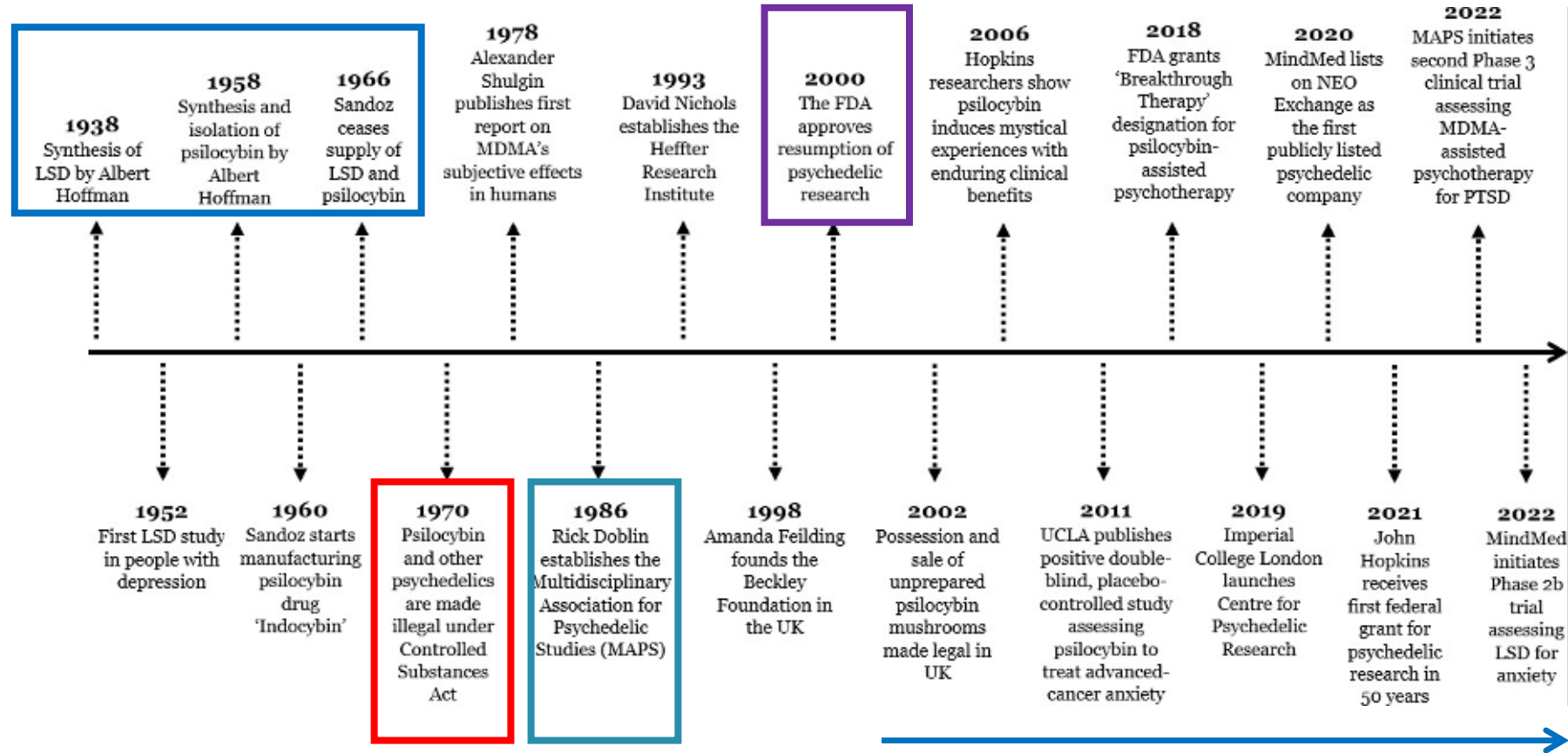
Public interest in psychedelic-assisted therapy is will grow, particularly among people with lived experience. Adverse events will not be common, but are likely to increase (as is misconduct by therapists).

Governments will face unanticipated regulatory challenges, possibly in reaction to court decisions

Professional regulators will be responsible for emerging practice considerations (including providers, training, and treatment sites).

The Evolution of Clinical Trials for Psychedelics in Mental Health: What is already here, What is needed, What is next?

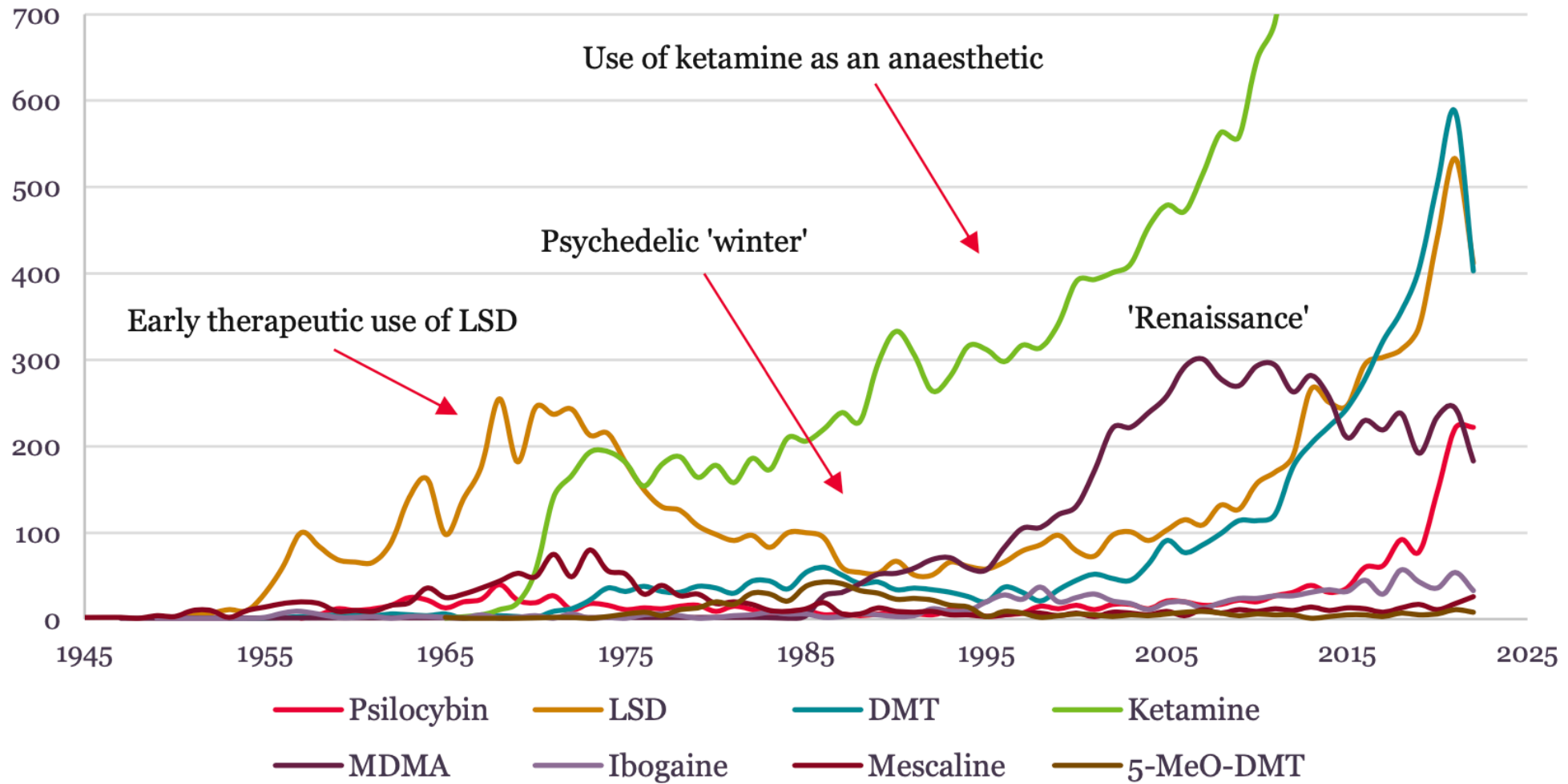
A TIMELINE OF PSYCHEDELIC HISTORY



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- Psychedelics quickly **got into clinics during the 50s and 60s** as adjuncts to psychotherapy, but their widespread recreational use caused criticism. These substances became damningly portrayed by the media after allegedly reports of dangerous trips and suicide attempts
- **The war on drugs** had a significant impact on further stigmatizing psychedelics, leading to their classification as Schedule 1 substances – i.e., with limited/questionable therapeutic utility and high potential for abuse. Mainstream clinical research was stalled for decades, while regional practices and cultural traditions involving psychedelics remained strong.
- Interestingly, **the resurgence of psychedelics in the early 2000s** was in part due to the interest in a non-hallucinogenic compound, ketamine, and its rapid antidepressant effects

Number of psychedelic research papers has exploded in the last century



Source: PubMed - date accessed: 26/09/22, H&P estimates



Current FDA Landscape

New IND Applications to DP: 2000 to 2021



Unpublished internal analysis; includes research and commercial INDs
Psychedelics included: ayahuasca, DMT, LSD, MDMA, psilocybin

Set and Setting

Set refers to the **mindset** of the study participant/patient.

It includes the **attitudes, expectations, and intentions** that the participant has, and encompasses how they feel about the upcoming experience – including this person's beliefs, hopes, fears, personality.....

.....**hence the vital role of preparation sessions.**

What is true for the study participant is also true for each person who will be in the room, as they are part of the process, relationship, and setting.

Setting includes physical space, location, the room you will be meeting in with the study participant.

Aesthetics, furniture, bathroom location, noise level, lighting, audio-video equipment, nourishment, and equipment are all part of the research setting.

Many cultures using psychedelics for religious and ceremonial healing reasons utilize **an outdoor setting with group involvement**. For some, this enhances their feeling of interconnectedness with nature and their communities.

Different settings...different purposes



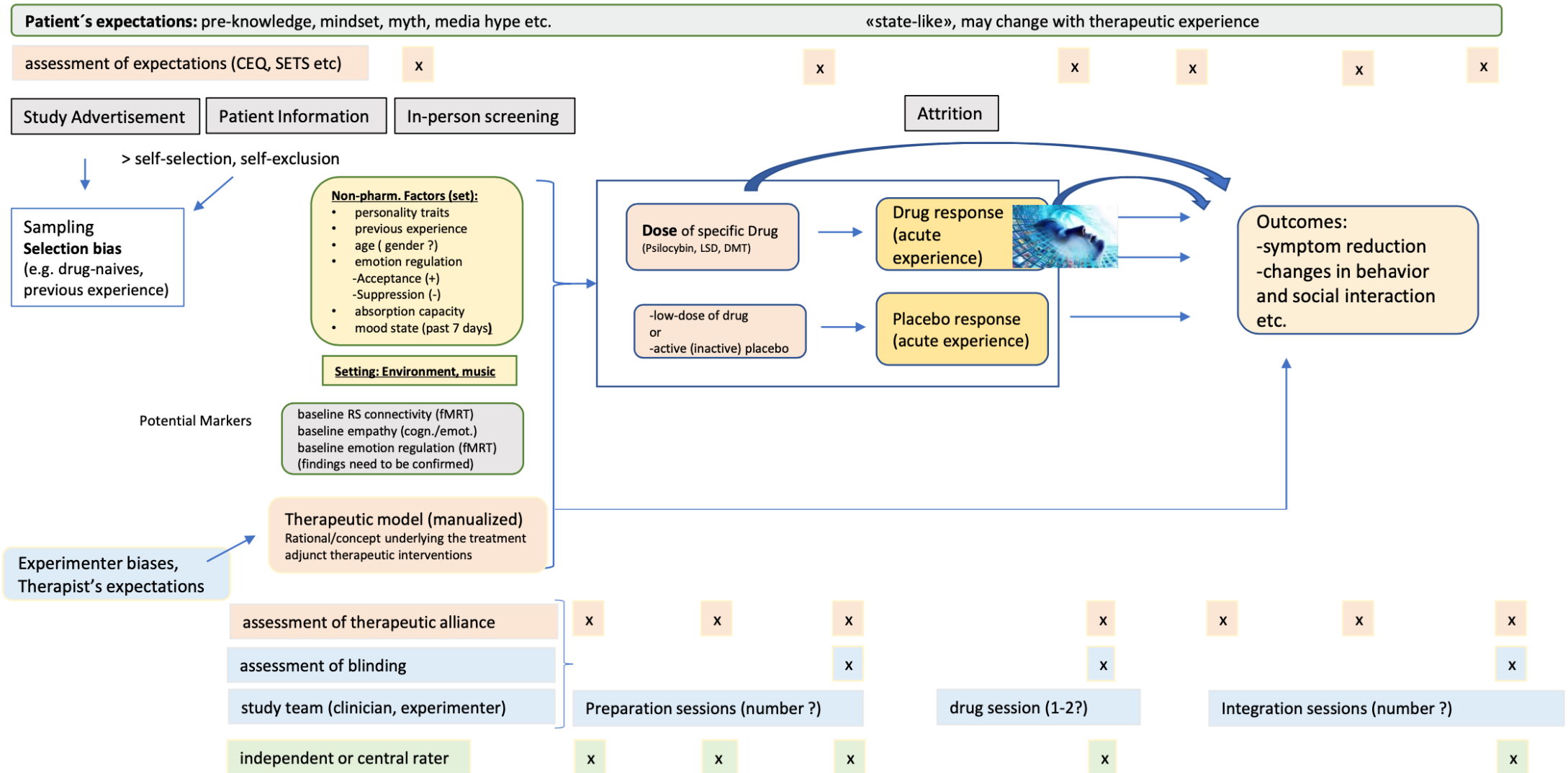
Example Psychedelic Psychotherapy Components

Preparatory Psychotherapy	Drug Treatment Session	Integrative Psychotherapy
<ul style="list-style-type: none">• Series of meetings (e.g., 4 x 2-hour sessions in month prior to drug treatment) between patients and monitors/therapists• Discuss meaningful life experiences, beliefs, goals	<ul style="list-style-type: none">• Monitors/therapists offer gentle guidance, support, and reassurance as needed• Encouragement to “trust, let go, be open” to experience• Instrumental music, eyeshades to block distractions	<ul style="list-style-type: none">• Series of meetings (e.g., next-day session + 2 additional sessions over 6 months) between patients and monitors/therapists• Discuss novel thoughts and feelings that arose during drug treatment session
<p><u>Goal:</u> Prepare patient for drug treatment, build trust/rapport establish intentions/goals</p>	<p><u>Goal:</u> Reduce adverse psychological reactions, facilitate therapeutic session</p>	<p><u>Goal:</u> Ensure psychological stability, process and integrate experience</p>

Johnson, Richards, & Griffiths. *Journal of Psychopharmacology* (2008)

Multiple factors that may influence the Dynamics of Psychedelic Experience and Outcome

Multiple factors that may influence the Dynamics of Psychedelic Experience and Outcome



Practical Challenges for conducting psychedelics research

- **“Learning curve” for Institutions – Hospitals, REB, etc.**
- **New challenges for protocol design and implementation**
 - Privacy/confidentiality
 - Caregivers’ involvement, ICF
- Similar questions and challenges we faced in early days of research involving new imaging techniques, genetics, etc.
- **Stigma** – impact on recruitment of potential study participants
- **Health Canada Regulations** - IP storage, dispensing
- **Funding mechanisms** - limited federal funding, uncertainties in the corporate world: new area of research.... or a fad?

Q & A



Session Wrap Up

- Thank you for joining us!
- Please fill out the feedback survey following the session—a link has been added into the chat

Thank You



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