

# LABORATORY OF THE FUTURE?

## AUSTRALIA'S PRESCRIPTION PSYCHEDELIC ROLL OUT AND OTHER INNOVATIONS IN THE LAND OF OZ

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# PSYCHEDELIC SCIENCE AFFILIATIONS & DISCLOSURES

**Founder, Head:** Clinical Psychedelic Lab, Dept Psychiatry, Monash University (Aus)

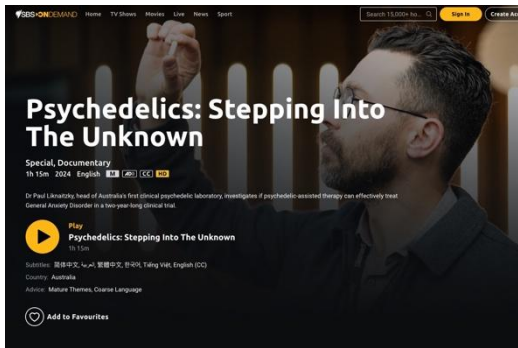
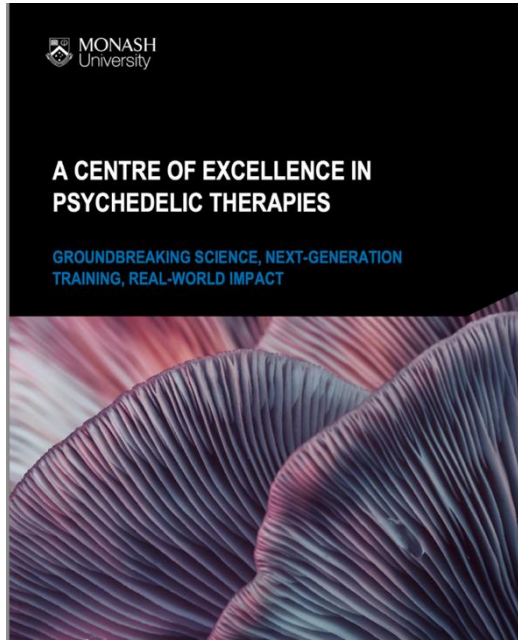
**Adjunct Senior Research Fellow:** School of Psychological Sciences, Monash University (Aus)

**Scientific Advisory:** MIND Foundation (Germany); Natural Medtech (Aus); Emyria (Aus); Toga Health (Aus); Otsuka (USA)

**Research funding:** MRFF (Australian Government); Beckley Psytech (UK); Cybin Inc (CA); Incannex Healthcare (Aus/USA); Multidisciplinary Association for Psychedelic Studies (USA).

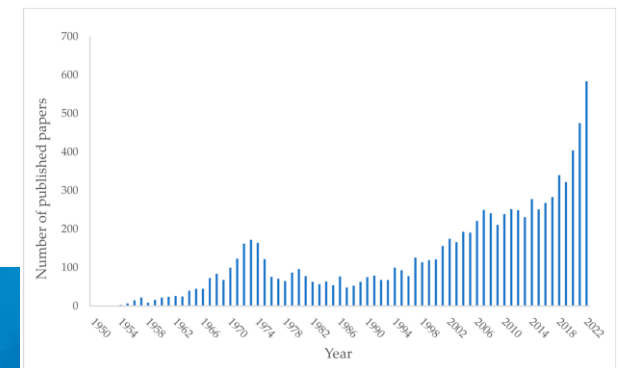


# AUSTRALIA'S FIRST PSYCHEDELIC LAB



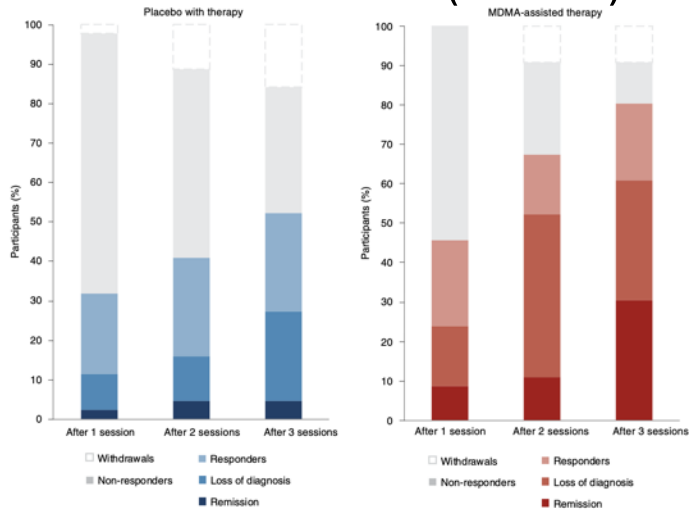


# PSYCHEDELIC PSYCHIATRY – SECOND WAVE

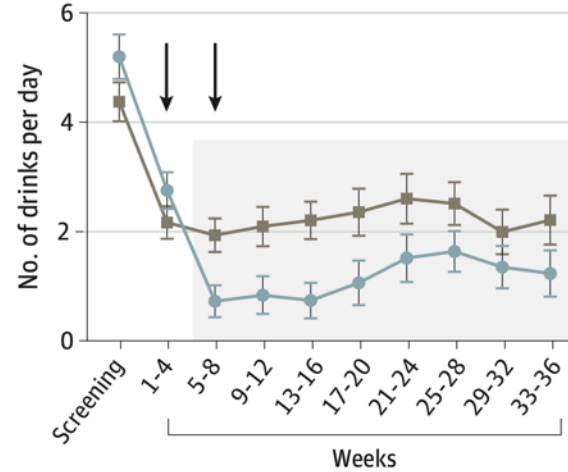


# WHAT'S ALL THE EXCITEMENT ABOUT?

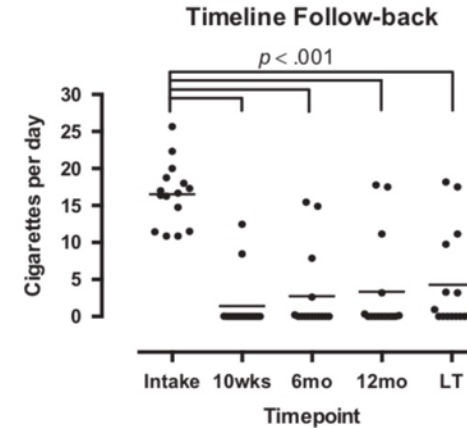
## MDMA/PTSD (MAPS)



## Psilo/AUD (NYU)

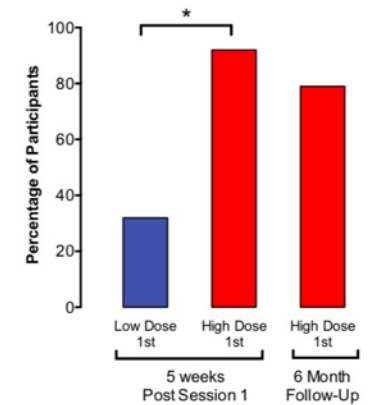


## Psilo/Smoking (JHU)

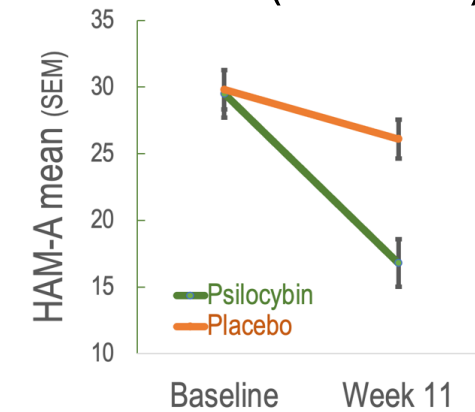


## Psilo/EoL Distress (JHU)

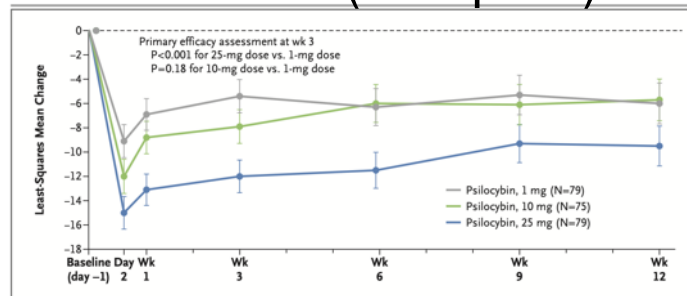
GRID-HAMD (Depression)  
Clinically Significant Response



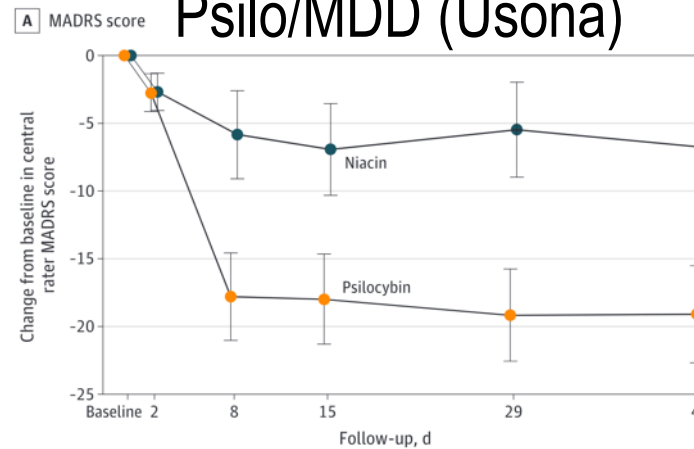
## Psilo/GAD (Monash)



## Psilo/TRD (Compass)

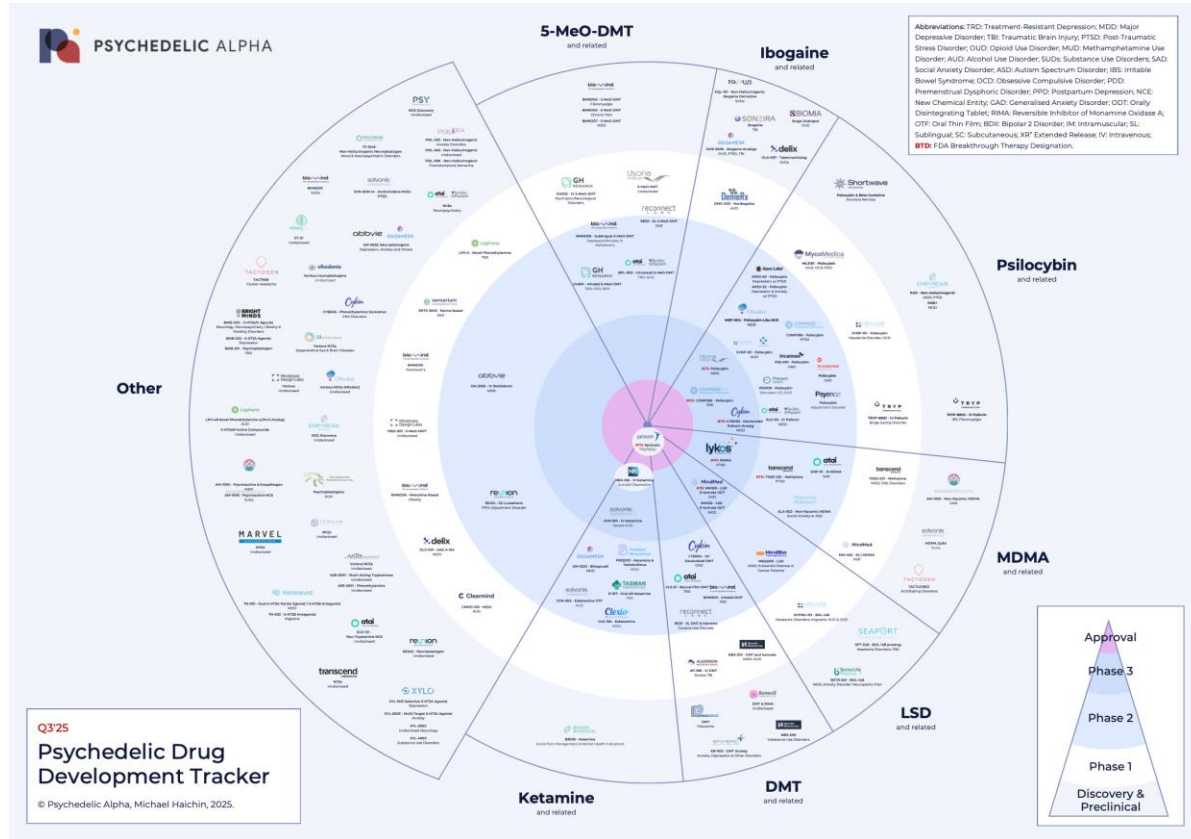


## Psilo/MDD (Usona)

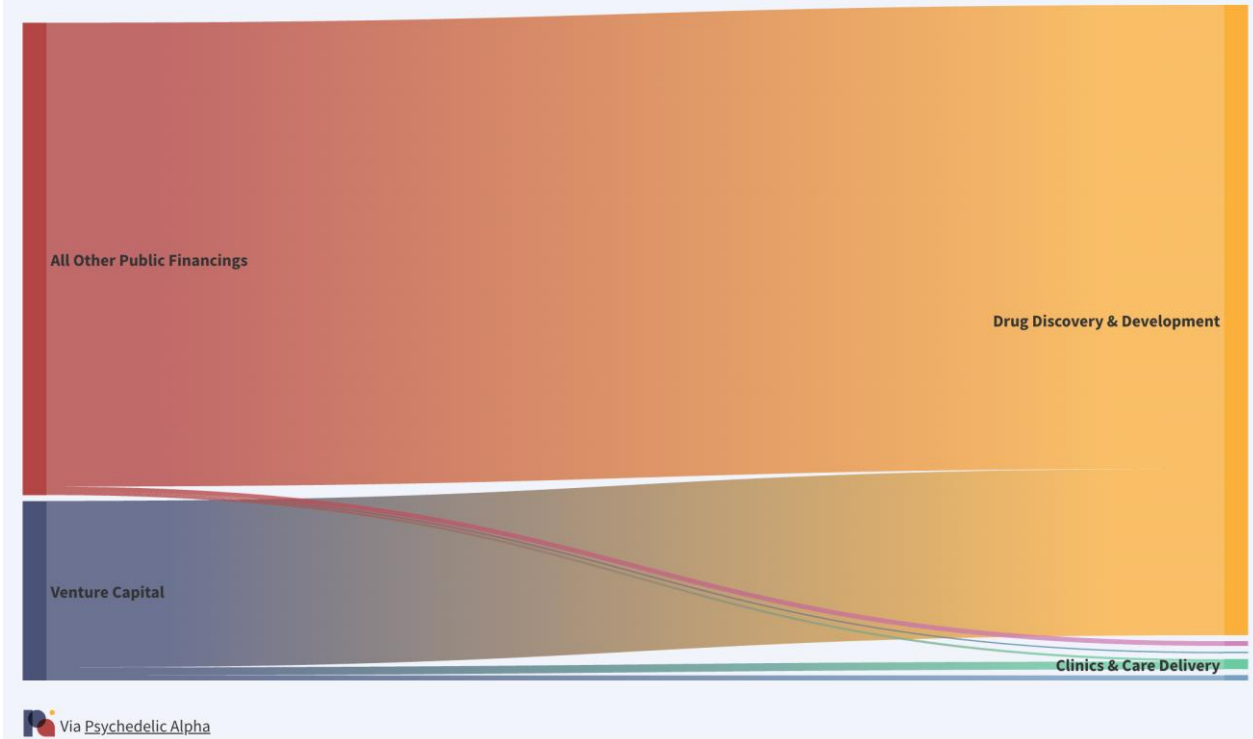


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# WHERE ARE WE HEADED? ...FOLLOW THE MONEY



## Sources & Uses (2017 - Q1 2025)



# The PAT field is drifting toward 'narrowness'

- **Narrow Targets** → Symptoms, late-stage pathology; misses prevention, wellbeing, contextual drivers ...
- **Narrow Training** → Basic support, manuals, knowledge; misses the centrality of relationship, personal-professional dev, therapeutic character/presence ...
- **Narrow Translation** → Products, usual-care; misses psychedelic-specific, system-level design...







# **INNOVATION IN:**

**1. ACCESS**

**2. REGULATION**

**3. IMPLEMENTATION**

# **ACCESS: DOWN- SCHEDULED PSYCHEDELICS**

# WORLD-FIRST DOWNSCHEDULING

- Bifurcated down
- MDMA for PTS
- Psychiatrists (+
- Application to H
- Application to T
- Some State/Ter
- RANZCP guidel
- Announced 3<sup>rd</sup>



Australian Government  
Department of Health and Aged Care  
Therapeutic Goods Administration

MDMA (3,4-methylenedioxy-  
amphetamine) and psilocybin for  
therapeutic purposes  
for psychiatrist prescribers

January 2023



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# THE AUTHORISED PRESCRIBER SCHEME

At recent update, Sep 2025:

- MDMA APs = 30
- Psilocybin APs = 26
- Total unique patients treated with MDMA = 87
- Total unique patients treated with psilocybin = 47

Schedule 10 – prohibition of sale, use and supply

Schedule 9 – prohibited substances

Schedule 8 – controlled substances

Schedule 7 – dangerous poisons

Schedule 6 – label use of poison

Schedule 5 – label use of caution

Schedule 4 – prescription only medicines

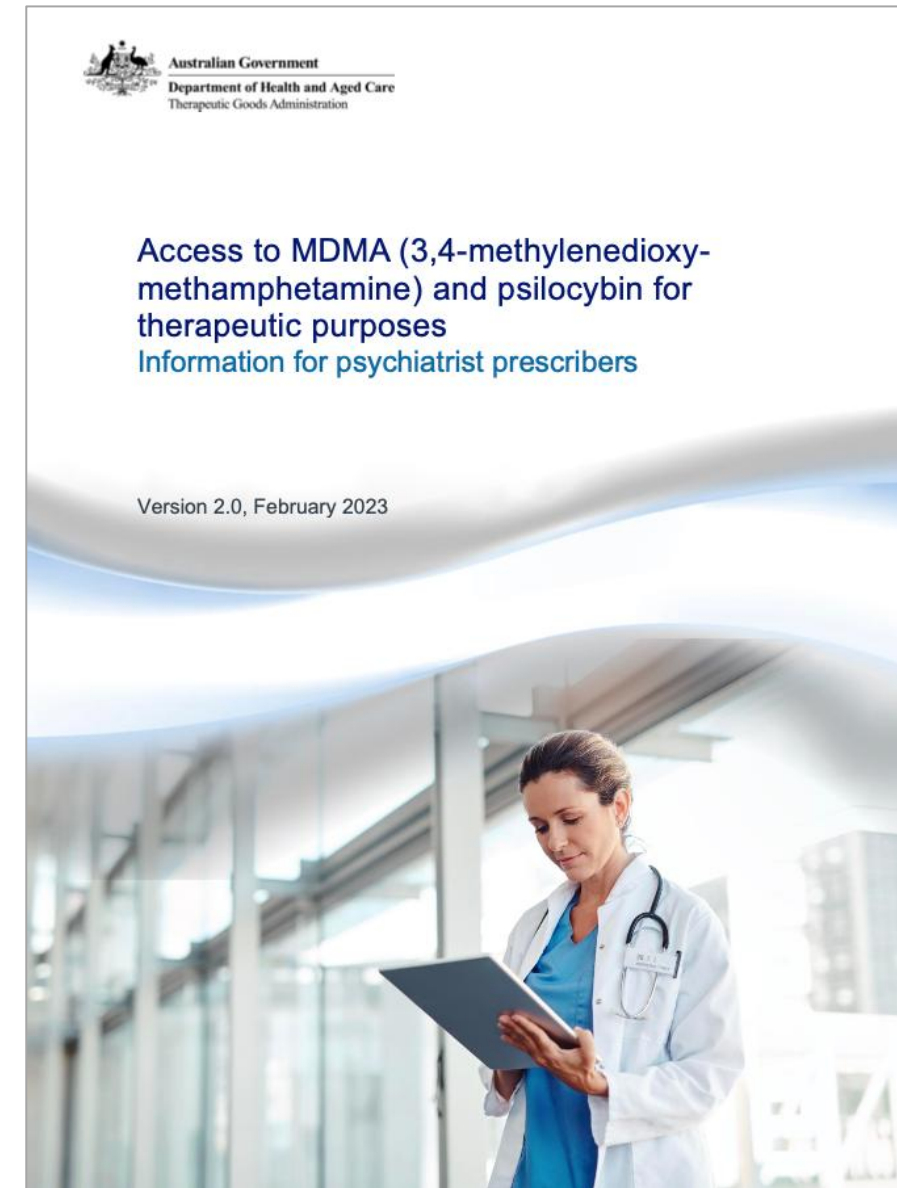
Schedule 3 – pharmacist only medicines

Schedule 2 – pharmacy medicines

# WORLD-FIRST DOWNSCHEDULING

## CONCERNS

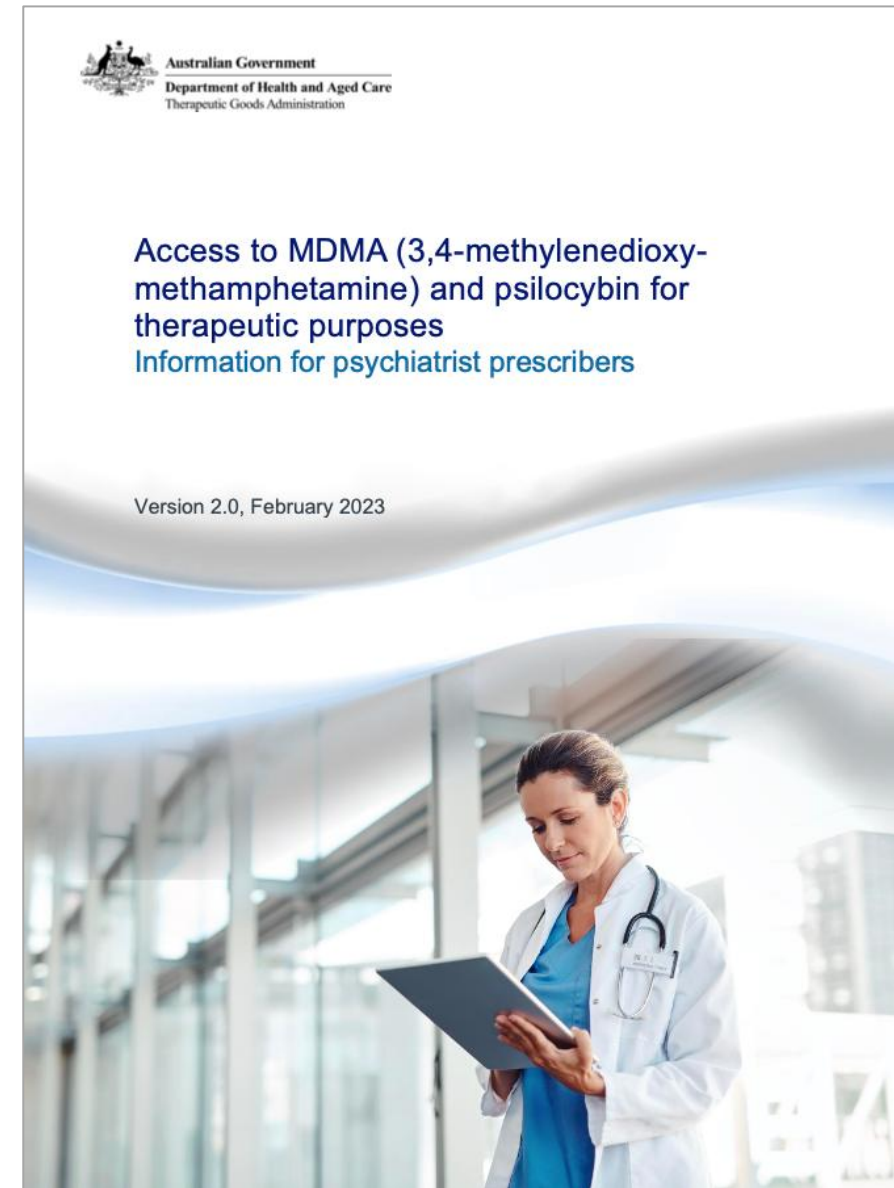
- Rolled out too quickly – particularly in Aus context?
- Inadequate monitoring, not harmonised?
- Inadequate reporting, not public?
- No working group or formal collaborative learning process established?
- **Does not afford multisite best-practice development**



# WORLD-FIRST DOWNSCHEDULING

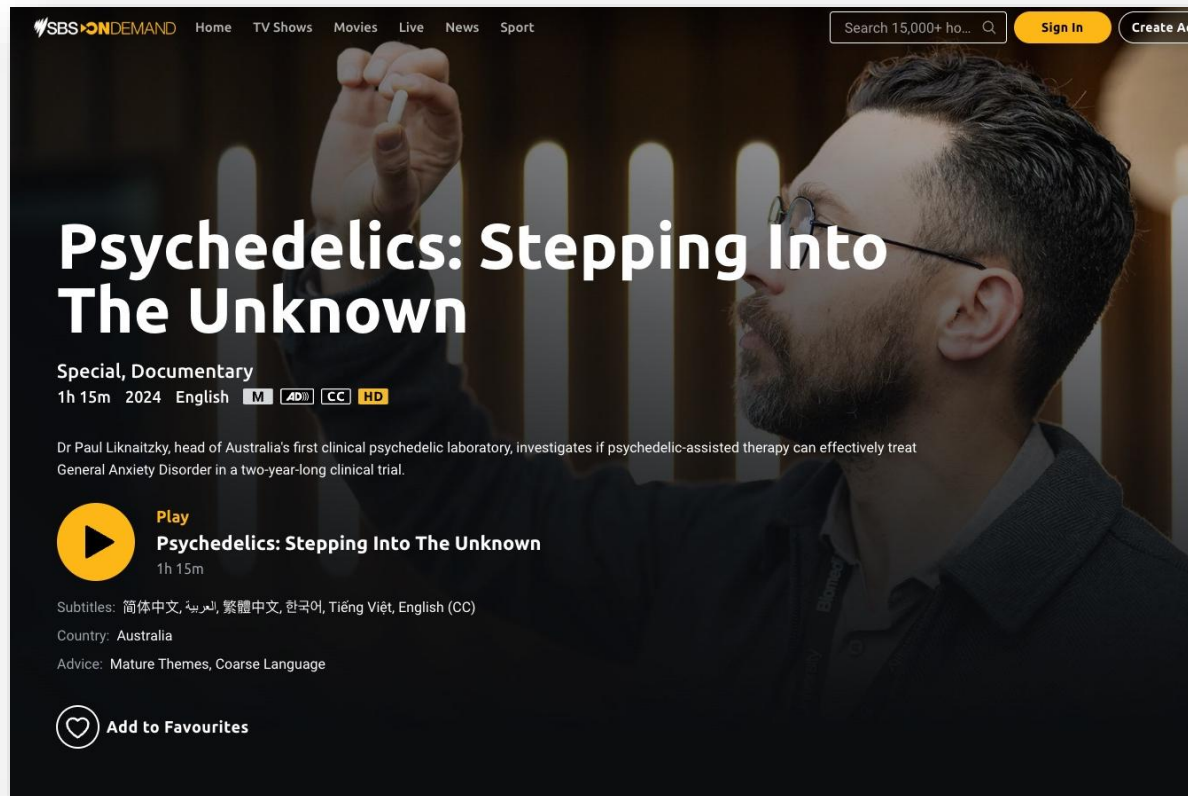
## COMFORTS

- Numerous guardrails – HREC, RANZCP, TGA, state Gov, drug + therapy, AP/therapist training...
- Opportunity to successfully treat greater number and diversity of patients?
- Real-world implementation – develop best-practice, train professionals, assess cost-effectiveness, etc?
- **May afford a ‘soft launch’:** compared to drug approval, more barriers to entry, guardrails, caution, scrutiny... (and likely capacity development).`





# WORLD-FIRST DOWNSCHEDULING



# **REGULATION: TOOLS NOT TREATMENTS**

# TOOLS NOT TREATMENTS





# TOOLS NOT TREATMENTS

- Addressing the '**liability**' of psychotherapy for pharma R&D
- Psychedelics as tools, not treatments: a la **anaesthetics**
- Reframing Psychedelic Regulation:
  - Product regulators can focus on '**therapeutic states**' as endpoints (e.g., distress tolerance)
  - Practice regulators can focus on procedure (medical, psychotherapeutic)
- Implications:
  - **Averts 'race to the bottom'** in psychedelic practice
  - Supports **best-practice** development
  - Dramatically **expands 'addressable market'**!



# **IMPLEMENTATION:** **FIFO-PAT**

# KEY CHALLENGES FOR PAT CLINICS

- Expensive
- Clinics few and far between
- Protocols not adequately tailored
- Limited continuity-of-care
- Difficult to determine client suitability
- Opportunity for durable outcomes can be missed





# THE FIFO-PAT APPROACH

- Cheaper
- Location-independent
- Tailored
- Preserves continuity-of-care
- Improves screening / suitability
- Potential for more durable outcomes?



# FIFO-PAT-201 OVERVIEW

- **Rationale:** Distributed model of PAT in community may be more accessible and beneficial
- **Design:** Sequential, randomised, TAU-controlled trial
- **Intervention:** Psilocybin-assisted psychotherapy with self-directed extended integration adjuncts
- **Participants:** 30 people with Major Depressive Disorder
- **Outcomes:** Feasibility, safety, acceptability, preliminary efficacy:  
↓ depression, ↑ functioning



Sekula

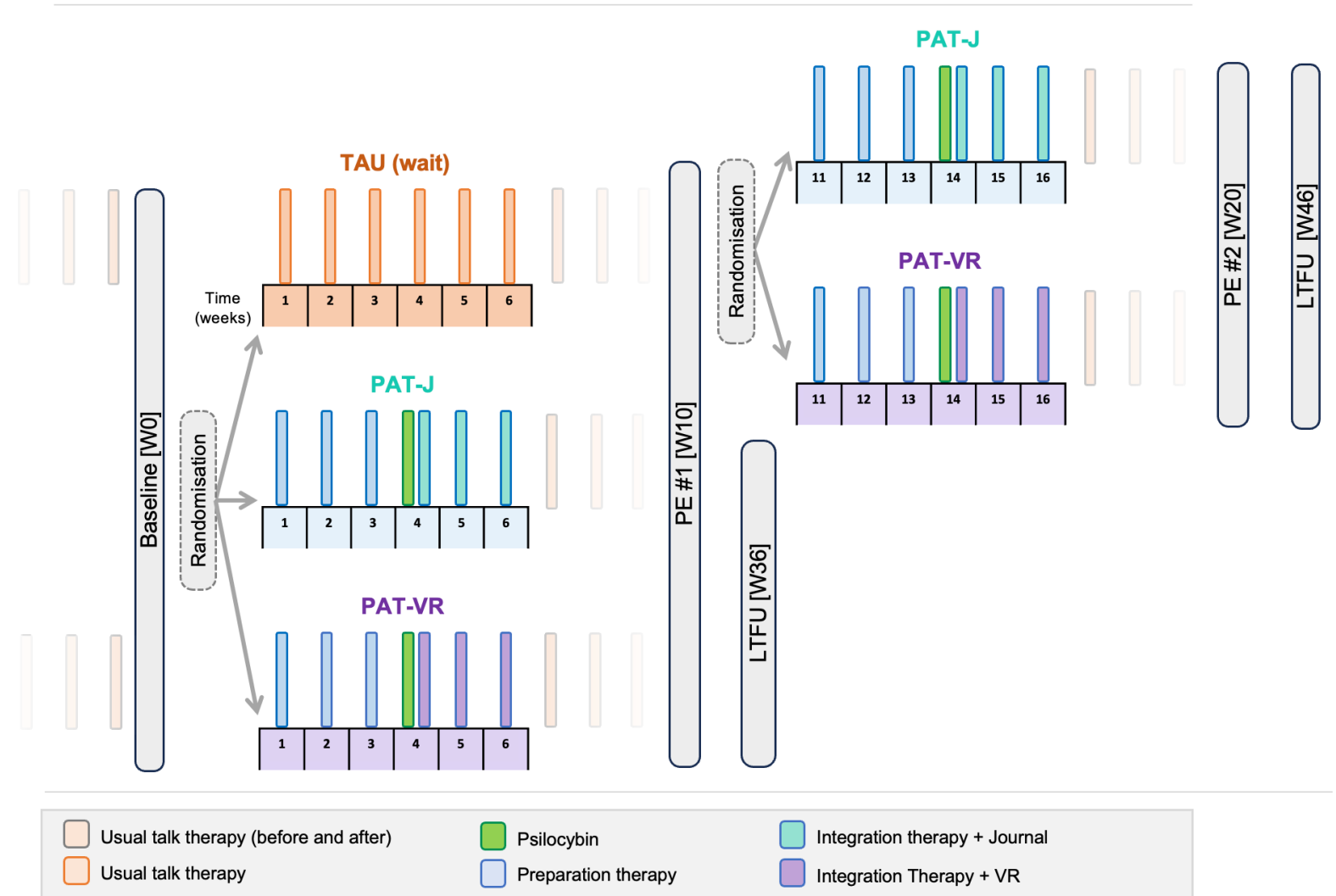


Puspanathan



Spektor

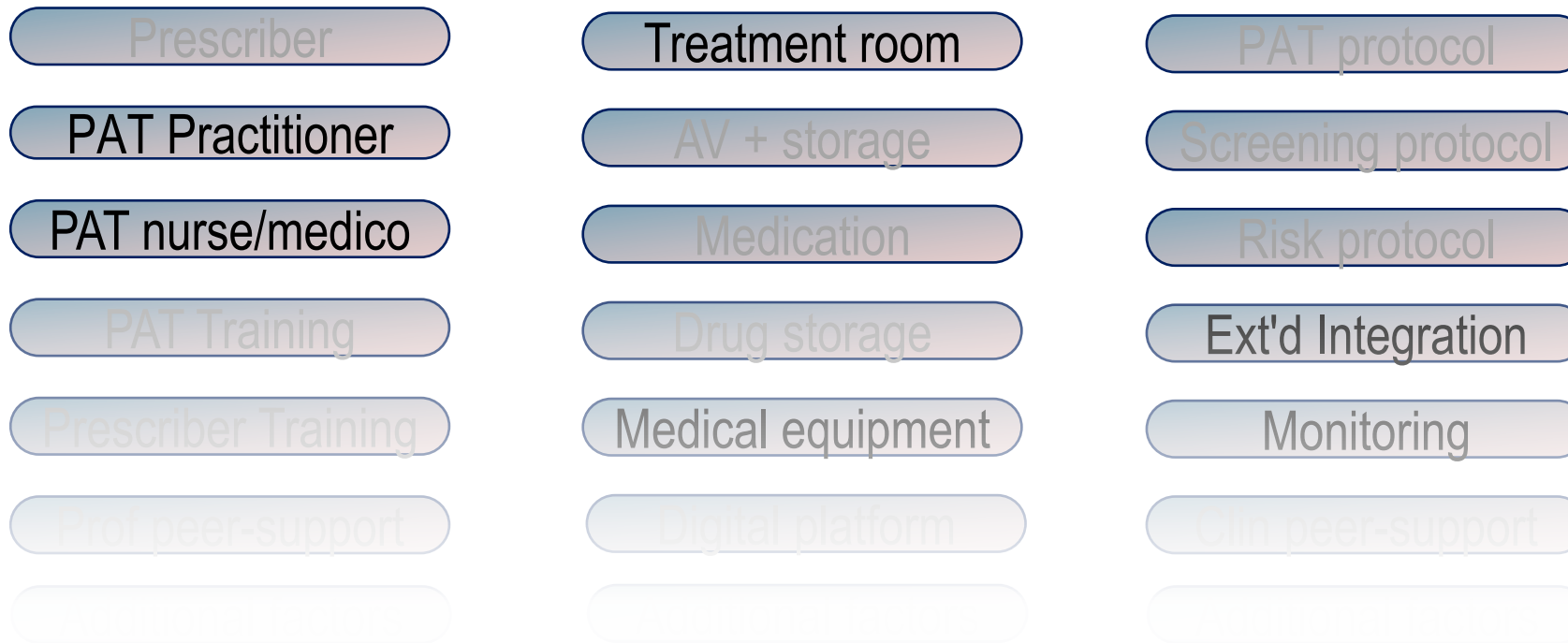
# FIFO-PAT-201





# TRANSLATIONAL R&D: BEYOND PRODUCTS

Developing modular, distributed system-level design for service quality: training, supervision, protocols, infrastructure, monitoring, community, compliance, approvals...



# TRANSLATIONAL R&D: BEYOND PRODUCTS

Developing modular, distributed system-level design for service quality: training, supervision, protocols, infrastructure, monitoring, community, compliance, approvals...

Prescriber

PAT Practitioner

PAT nurse/medico

PAT Training

Prescriber Training

Prof peer-support

Treatment room

AV + storage

Medication

Drug storage

Medical equipment

Digital platform

PAT protocol

Screening protocol

Risk protocol

Ext'd Integration

Monitoring

Clin peer-support



# TRANSLATION: BEYOND PRODUCTS

- **Counterpoint to quality decay:** Pharma R&D and regulation drifting pharmaco-centric, constrained within standard care models/contexts
- **System design and integration:** Protect PAT-specific therapeutic integrity while bridging into health services
- **Dual mandate:** Solve simultaneously for access and quality

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