	RIPE		October			2025	
	Today's agenda						
$\rightarrow$	Index						
	1. Why Europe must act now	2. Roadmap to access	3. Cost of inaction	4. Sever		5. The tear for this mis	
	The massive opportunity and the high cost of delay.	De-risking the path from regulatory approval to reimbursement.	Preventing delays, regulatory pushback, and a patchwork approach.	A comprehe strategy to key access h	to overcome experts in p		/,
	6. Voices of RIPE support	7. What we need to start	8. Execution timeline	9. Fundi governa	•	10. Be part RIPE	t of
	Our growing network of influential partners and supporters.	The seed funding required to launch our pilot phase.	A phased plan with clear, time-bound, measurable deliverables.	A robust str independer and efficien deploymen	nt oversight t	An invitation to become a found partner today.	ding

	October	2025							
Why Europe must act now									
Europe Stands at a Crossroads									
The success of late-stage clinical trials for psychedelic therapies presents two clear paths forward for European mental healthcare.									
without action	A Prepared Future	with RIPE							
National HTA bodies struggle with novel therapies, rejecting on technicalities, not merit.	Evidence-Based Acceptance & Value Recognition	We'll equip HTAs and payers wit optimised evidence and modelli methods for value assessments.							
Without standard pathways, access becomes fragmented and unfairly distributed.	Clear, Unified Reimbursement Pathways	We'll design payment and reimbursement models before launch, easing implementation.							
Payer hesitation and market uncertainty wastes decades of research and billions invested.	Accelerated Patient Impact & Economic Return	Prepared systems enable equita access, unlocking recovery pote and ROI.							
	without action  National HTA bodies struggle with novel therapies, rejecting on technicalities, not merit.  Without standard pathways, access becomes fragmented and unfairly distributed.  Payer hesitation and market uncertainty wastes decades of	at a Crossroads  I trials for psychedelic therapies presents two clear paths forward for Europe  Without action  A Prepared Future  National HTA bodies struggle with novel therapies, rejecting on technicalities, not merit.  Without standard pathways, access becomes fragmented and unfairly distributed.  Payer hesitation and market uncertainty wastes decades of  A Prepared Future  Evidence-Based Acceptance & Value Recognition  Clear, Unified Reimbursement Pathways  Accelerated Patient Impact & Economic Return							

RIPE's sole purpose is to build the roadmap for the prepared future.

# The RIPE mission is to build a *structured*, *multi-year roadmap* to facilitate *tailored reimbursement evaluations* and support *equitable access* for regulatory approved psychedelic therapies in Europe.

	RIPE						October		2025			
	Roadmap to access											
Pathway to Pan-European Readiness												
Therapeutic Approval $ ightarrow$ HTA Acceptance $ ightarrow$ System Integration $ ightarrow$ Patient Access												
	H2 '25	H1 '26	H2 '26	H1 '27	H2 '27	H1 '28	H2 '28	H1 ′29	H2 '29	H1 '30	H2 '30	H1 '31
	Phase O	ne Building t	he evidence	base								
Phase Two Securing Reimbursement Pathways												
		Phase Three Design the Infrastructure & Funding Framewo					ng Frameworl	ks				
		Phase Four Enable Patient					tient Access					
	Phase One - Evidence			Phase Two - Reimbursement			Phase Three - Infrastructure			Phase Four - Access		
	We build the definitive economic models to quantify the value of these therapies to European health systems payers and broader society.			We proactively engage national assessment bodies (HTA) with our economic models and publish methodology guides.			We co-design the "nuts and bolts" of access, e.g. billing codes, validating outcomes-based payment frameworks, and creating blueprints for therapist training.		We consolidate our work into national "Access Playbooks" and support local partners in implementation.			

Roadmap to access

# Alternative Pathways to Access

The systemic pathways are the goal for equitable access. Understanding the full landscape reveals the urgency of making reimbursed care work.

#### Niche & Unsanctioned Systemic Pathways Market-Driven Pathways Prepared National Reimbursement Private Insurance Coverage Compassionate / Special Access The "gold standard" leading to broad, equitable Faster access for a limited, employed population. Pre-approval access for the most severe cases. Vital, access funded by national health systems and insurers. Creates a two-tier system and can be withdrawn easily. but unscalable and not a systemic solution. Modified / Conditional Reimbursement Private Out-of-Pocket Payment Medical Tourism & Underground Use The public health risk of inaction. Patients seek A potential outcome facilitating early access tied to The most inequitable route, accessible only to the real-world data collection to manage payer risk. wealthy. Drives a wedge between patients. unregulated care, driven by desperation.

RIPE's mission is to make the systemic pathways the most *viable* and *efficient* route, preventing a fragmented future dominated by inequitable and unregulated access.

Cost of inaction

# Bridging the Gap No Single Company Can

The central challenge is a fundamental mismatch between individual company incentives and collective system needs.

#### Individual Drug Developers

Focus on proving drug safety and efficacy for regulatory approval.

Perceived by payers as a biased commercial actor, unable to create system-wide, neutral infrastructure.

They build the car, not the public highway.

#### The European Health System

Requires independent economic models and standardized frameworks to justify investment and ensure quality.

Due to competing priorities and limited resources, health systems address new therapies only at product launch, not proactively.

This last-minute approach prevents the creation of robust, class-wide solutions, forcing rushed, ad-hoc fixes that often restrict access.

This coordination and trust gap is where promising therapies fail. It's not a scientific failure, but a *system failure*. RIPE was purpose-built to be the neutral, expert bridge that closes this gap.

Cost of inaction

# De-Risking the European Market

Act NOW	Wait 2 Years	Do Nothing		
We proactively shape the environment, build trust with payers, and create a prepared market with key challenges de-risked.	We fight an uphill battle to reverse entrenched skepticism and hastily-made, restrictive policies.	We risk repeating the gene therapy story. An unpredictable landscape of reimbursement rejections and delays. Creating inequitable patient access and makes Europe a low-priority market. A lost decade.		
Chance of broad EU access MEDIUM to HIGH	LOW	SYSTEM REJECTION		

RIPE is the ultimate leverage point. A relatively small, early investment in building this neutral, collective infrastructure dramatically de-risks the multi-billion Euro opportunity for psychedelic medicine in Europe.

# The Engine Behind Our Roadmap

# Build the evidence



Forge the alliance



Implement the solutions

This is the foundational work we start now.

We create the indisputable case for access
by quantifying value & mapping the terrain.

We build the coalition now to create a unified voice and engage key decision-makers early and effectively. implement the solutions

Based on our evidence and alliances, we will pilot and design the practical tools for real-world implementation.

- Health Economic Analysis + Societal Value
- 2. Reimbursement Pathway Evaluation

- 3. Stakeholder Alignment & Alliance
- 4. HTA & Payer Engagement

- Reimbursement Framework Design & Validation
- . Funding & Billing Infrastructure

7. Multi-disciplinary Forums

All work is supported by multi-disciplinary forums to maintain trust and momentum across the ecosystem.

Our strategy addresses every stage of the reimbursement problem: proving the value, uniting stakeholders, and building the tools for access.

The team for this mission

# Meet the Architects of Access



Lia Mix, LMFT, CPTR
Founder & CEO
Delphi



Martin Gisby, PhD

Founder

Magnetar Access



Floris Wolswijk, MSc
Founder
Blossom

#### US System Integration & Payer Strategy

- 20+ years' experience integrating new behavioural health therapies into the US healthcare system.
- Directly secured insurance coverage impacting 20 million lives
- Bridges the clinical, commercial, and regulatory worlds.

#### European Market Access & HTA Expertise

- 17+ years' experience navigating complex European pricing and reimbursement systems.
- Proven track record launching innovative medicines across the EU.
- Deep, practical knowledge of national HTA processes.

#### Psychedelic Ecosystem Intelligence

- Founder of Blossom, the leading data and insights platform for the psychedelic industry.
- Maps the scientific, clinical, and commercial landscape.
- Translates complex research into actionable intelligence.

RIPE combines deep U.S. precedent with on-the-ground European expertise and unparalleled ecosystem knowledge.

We are actively recruiting a network of technical and country-specific experts to support our mission.

# Advocates for the RIPE Initiative

Clerkenwell Health

RIPE is not working in isolation. We are supported by key European and global organisations in psychedelic science, policy, and innovation.



World-renowned independent science body providing trusted fiscal sponsorship and UK-based advocacy.



Pan-European alliance accelerating evidence-based policy and access to transformative psychedelic therapies.



FOUNDATION

Championing education and developing pioneering access models in the Netherlands, a key early market.



Brussels-based innovative mental health association of researchers, NGOs and companies.



DC-rooted, nonpartisan nonprofit uniting lawmakers, researchers, and patients to safe, evidence-based psychedelic therapies.



European Citizens' Initiative (ECI) aiming to create guidelines, boost funding for research, and adopt a common EU stance.













Voices of support

# Endorsed by Leaders

Our approach is validated by leaders who recognise the urgent, practical need to prepare our systems for this class of therapies.

#### Policy

"For 50 years, our approach to new treatments has been hampered by outdated thinking. Specifically, we need to break down the outdated barriers to psychedelic research.

Winning the scientific argument is only half the battle. We must now put in place the economic and implementation frameworks to allow new treatments to succeed.

RIPE's proactive, evidence-based work is essential to ensure these therapies can actually be delivered through the NHS, fulfilling their promise for patients."



Jeff Smith MP
Labour MP Manchester Withington
Government Whip, Lord Commissioner of HM Treasury

#### Advocacy

"A new therapeutic paradigm is approaching Europe's health systems. History shows that without proactive preparation, these systems will react with inconsistent, last-minute policies that stifle innovation and ultimately fail patients.

RIPE's mission is to get ahead of this; to build the scientific, economic, and ethical frameworks now, so that patient access is governed by sound strategy, based on the latest scientific evidence not reactive politics."



Anne Katrin Schlag, PhD Acting CEO & Head of Research *Drug Science* 

Voices of support

# Endorsed by Leaders

Our approach is validated by leaders who recognise the urgent, practical need to prepare our systems for this class of therapies.

#### **Health Economics**

"Psychedelic-assisted therapy is a complex intervention with profound, long-term benefits. Health economics is the essential discipline that translates these complex outcomes into the language of value that payers and health systems understand.

Building this translation capacity in Europe, as RIPE aims to do, is a critical step towards ensuring rational and equitable access."

#### Clinical

"The fascinating and paradigm-shifting convergence of pharmacology and psychology in these novel treatments is likely to pose significant challenges to their integration into healthcare systems.

This is why I believe the reimbursement roadmap initiative is both timely and essential. It will provide much-needed, expert guidance to help European mental healthcare systems prepare for the large-scale, effective implementation of these therapies."



Elliot Marseille, PhD
Director Collaborative for the Economics of
Psychedelics UC Berkeley



David Erritzoe, MD, PhD, MRCPsych Deputy Head *Imperial Centre for Psychedelic Research* & Head of the *CIPPRes Clinic* 

**RIPE** October 2025 What we need to start Igniting the Mission With a €100k seed investment locked in before end of October 2025, we can move from planning to immediate, high-impact action. Forge a Coalition Master Blueprint This funding allows us to fully map out our 4-phase We will bring together 25+ leaders and experts from strategic roadmap. policy, HTA, clinical, and patient communities. Deliverable: A comprehensive "European Deliverable: A publicly endorsed reimbursement and Reimbursement and Access Blueprint" that will serve as access Blueprint, accompanied by a Joint Statement of the guiding document for the entire RIPE mission and Action from leading organisations, pledging to the basis for the subsequent scale round. collaborate on implementing the path forward. RIPE's goal is to have these two foundational assets—the Blueprint and the Joint Statement—firmly established by early 2026. This is the foundational work that clarifies the longer-term RIPE workplan and allows us and our partners to confidently execute on all elements of the reimbursement and access mission.

# Our 3-Stage Sprint to Deliver the Blueprint & Alliance

# Activation & research $\rightarrow$

- Secure seed funding & establish governance with Drug Science.
- Kick off foundational research for the Master Blueprint.
- Begin recruitment of foundational partners for the Working Group.

Outcome: The project is live and the core workstreams are activated.

# Execution & convening $\rightarrow$

- Conduct the core deep-dive interviews with system leaders.
- Host the Working Group to build consensus on key activities for the reimbursement and access roadmap.
- Draft the initial version of the "European Reimbursement and Access Blueprint."

Outcome: The coalition is formed and core strategic insights are gathered.

#### Consolidation & launch

- Finalise the comprehensive European Reimbursement and Access Blueprint.
- Release the Joint Statement of Action together with collaborative partners.
- Use these two powerful assets to secure funding for the first phase activities.

Outcome: A concrete plan with industry-wide buy-in, ready to scale.

This structured sprint ensures we deliver maximum value from the seed investment, culminating in a fully de-risked and actionable plan.

# From the Blueprint to Impact

Seed funding	Scale phase	Early 2026 Onwards		
<ul> <li>Master Blueprint:         The comprehensive, detailed strategic plan for European access.     </li> <li>Joint Statement of Action: The public commitment from our expert Working Group,</li> </ul>	Build the Evidence  Primary Goal: Create the definitive economic case for PAT in Europe.  • Pan-European Cost-Benefit Analysis  • Evidence Synthesis & Dossier Template	Secure Reimbursement  Primary Goal: Equip HTA bodies and payers with tools & methods.  • HTA Methodology Toolkit  • European Payer Observatory &	Design Infrastructure  Primary Goal: Design the "nuts and bolts" required for therapies to be delivered & paid.  • Core HTA Data Needs Guide  • Therapist Training &	Enable Access  Primary Goal: Translate our pan-European frameworks into country-specific guides  National "Access Playbooks"  Equitable Access
providing the mandate to execute the Blueprint.	• Real-World Evidence Collection Framework	Precedent Tracker	Competency Framework  • Clinical Service Delivery Blueprint	Framework & Policy Recommendations

The Master Blueprint & Joint Statement we create with seed funding will provide the detailed plan and mandate to execute this full workplan.

# Responsible Governance & Strategic Allocation

#### Our governance

Drug Science (Fiscal Sponsor)

Holds and disburses funds against milestones.

RIPE Executive Team

Executes the day-to-day mission.

Independent Steering Group

Provides strategic guidance and ensures mission integrity.

Seed budget



60% 25% 15%

Research & Blueprint Development - 60%

This is the core intellectual work. It funds the expert time required to conduct deep-dive interviews with HTA and payer leaders, analyse different country pathways, and synthesise this knowledge into the comprehensive "European Reimbursement and Access Blueprint."

Working Group & Joint Statement - 25%

This funds the structured process of building our expert coalition. It covers professional facilitation for high-impact workshops, development of strategic materials, and honoraria to secure dedicated time from key experts, including crucial patient representatives.

Operations & Governance - 15%

This covers the essential infrastructure for professional execution. It includes the fiscal sponsor administrative fee, initial legal costs, and core communication tools.

This integrated structure ensures every Euro is managed responsibly, overseen independently, and deployed strategically.



# The time is RIPE. Join the initiative.

Join the €100k seed syndicate to provide the catalytic capital needed to build our Blueprint and Joint Statement

Commitment deadline: 30 October 2025



Floris Wolswijk Founder, *RIPE Initiative*  floris@blossomact.com blossomact.com/calendly 2025

Funds managed through Drug Science | Registered Charity 1150449

# Appendices

# Additional Voices of Support



#### **Priority Projects**

- 1. Evidence generation
- 2. Cost-benefit analysis
- 3. HTA methodology review





The Broken Promise of Gene Therapy in Europe







Extended Biographies of Project Leaders









# Additional Voices of Support

"This therapy gave me back my quality of life when I needed it most, but I was one of the lucky few.

RIPE is doing the essential work to change this from a lottery into a standard of care, so that every person facing a difficult diagnosis has the same chance to find peace."

"We know psychedelics have shown great promise for healing in clinical trials. Understanding the importance of delivery and accessibility has become increasingly clear across the extensive psychedelic research from every sphere. These substances require unique and personalised delivery models that demand a real focus on how the rubber will hit the road — allowing for the full and safe utilisation of these promising medicines. Taking them from clinical development to realised treatments in Europe will require focused, systematic approaches.

RIPE is playing a vital role in ensuring that this transition is done thoughtfully and effectively, so that implementation is not an afterthought but a core part of bringing these therapies to those who need them."

"At Psyon, we see the profound therapeutic potential of these treatments firsthand, but we also live with the daily reality of navigating a healthcare system that is not built for them.

RIPE's work to build the essential frameworks is fundamental to ensuring our clinical work can scale and reach the millions of patients who desperately need it."



Andrea Siclari
Patient Advocate
Participant in LSD clinical trial



Grace Blest-Hopley, PhD CSO NWPharma Tech Research Director Heroic Hearts Founder Hystelica



Stanislav Milotinský, Mgr. et Mgr. Founder, Therapist, Psychologist *Psycon Clinic*  Priority Projects on the RIPE Roadmap The RIPE mission is to build the complete, multi-year roadmap to facilitate tailored reimbursement evaluations and equitable access for regulatory approved psychedelic therapies in Europe. While our seed funding is focused on creating the overarching Master Blueprint and Joint Statement, we have already scoped out several high-impact, foundational projects that represent the core of our future work. Phase One The Core HTA Data Needs Guide Phase One Pan-European Cost-Benefit Analysis Phase One & Two The HTA Methodology Toolkit

October

RIPE

The following slides discuss these three projects that are designed to be modular and can be initiated as soon as funding is secured.

We welcome conversations with partners interested in directly funding a specific, high-leverage workstream to accelerate progress in a key area.





# The Broken Promise of Gene Therapy in Europe

Groundbreaking science is not enough. Without preparing the system, innovation fails patients.

#### The Promise

Gene therapies represented a paradigm shift in medicine: one-time, potentially curative treatments for devastating genetic disorders.

Companies like Bluebird Bio brought revolutionary products like Zynteglo to market with regulatory approval from the European Medicines Agency (EMA), offering immense hope to patients with rare diseases.

After EMA authorisation, developers expected HTA and price negotiations, followed by routine patient access.

#### The Reality

Europe's health systems were not ready. Payers, faced with multi-million Euro upfront costs and uncertain long-term data, struggled to fit these one-time therapies into reimbursement models built for chronic care.

This led to a cascade of failures:

- Inconsistent & Unpredictable Decisions: Each country negotiated separately, leading to a "postcode lottery." A therapy available in one nation was rejected in another, creating deep inequities. There are only 20 cell and gene therapies licensed in Europe. vs. 43 in the U.S.
- Reimbursement Disputes & Market Withdrawals: After failing to secure reimbursement that reflected the therapy's value, Bluebird Bio famously withdrew both Zynteglo and Skysona from the European market. The system rejected the innovation.
- Eroded Investor Confidence: These high-profile failures sent a clear signal: Europe was a commercially unviable market for transformative therapies. This shook investor confidence and led companies to de-prioritize the continent.

This is the future scenario that the RIPE initiative has been created to prevent happening to psychedelic therapies.

# Martin Gisby, PhD

RIPE

Founder and Strategic Advisor, Magnetar Access

Healthcare industry specialist with experience spanning consultancy, biopharma, and innovative start-ups

Provides strategic advisory on market access and commercialisation of innovative therapies across Europe with a particular interest in psychedelic therapies

Past roles include: Head of Market Access - Europe and International for Jazz Pharmaceuticals

Recently co-authored report
"Reimbursement Pathways for
Psychedelic Therapies in Europe"

MSc in Biological Sciences and PhD in Biotechnology from The University of Manchester, UK

## Experience in Product Commercialisation - Europe & Ex-US

Product Development – Examples of disease areas with direct experience

- CNS
- o Major Depressive Disorder (MDD), PTSD, Schizophrenia, Bipolar Disorder, Epilepsy
- Oncology
- Acute myeloid leukaemia (AML), Acute Lymphoblastic Leukaemia (ALL), Chronic myeloid leukaemia (CML), Prostate Cancer
- Rare diseases
- o Polycystic Kidney disease (PKD), Narcolepsy, Gaucher Disease
- Acute care & Other
- ∘ VOD (post-HSCT), SIADH, Sleep Apnoea

Product Launches – Direct Responsibility for Pricing, Reimbursement and Market Access

- Vyxeos (AML) Jazz
- Defibrotide (VOD post HSCT) Jazz
- Erwinase (ALL) Jazz
- Sunosi (sleep apnoea & narcolepsy) JazzSamsca (SIADH) Otsuka
- Jinarc (PKD) Otsuka

Country Experience for PRMA

- Most European countries
- Canada, Australia, South Korea, Japan, Saudi Arabia, Brazil, Mexico, Colombia,

Turkev

# Martin Gisby, PhD

linkedin.com/in/martingisby/

#### Psychedelic-Specific Experience

Recent examples of advisory work

- Completed advisory work with 4 psychedelics developers over last 18 months across 5 therapeutic areas
- Co-author of 'Reimbursement Pathways for Psychedelic Therapies in Europe', published April 2025
- o First Europe-wide, payer-focused analysis of future reimbursement and access pathways for psychedelics
- o For developers, healthcare professionals, payers, policy makers and patients
- o Available at: <u>psychedelicsandreimbursement.com</u>
- Regular conference speaker / panellist discussing reimbursement of psychedelics and market access challenges
- o Psychedelic Science 2025, Breaking Convention (2025), Mental Health Resilience, Prague (2025), ICPR (2024)

#### Areas of advisory support and interest

- Regional pricing, reimbursement and market access strategies for assets
- o Indication / market assessments for commercial and reimbursement potential
- HTA needs and challenges with the psychedelics evidence package
- National and local implementation challenges and opportunities
- o Contracting and access agreements to support initial market access
- Value proposition development
- Business development in-licensing asset evaluation

Geographical areas of focus

• Europe, UK, Canada, Australia

# Lia Mix, LMFT, CPTR

US Healthcare System & Payer Experience

US healthcare system strategist and a pivotal figure in establishing the infrastructure for psychedelic-assisted therapy

Proven track record integrating novel behavioral health treatments into commercial insurance plans

Work has directly resulted in securing coverage for over 20 million people in the US

Combines 15+ years of health insurance system experience with a deep clinical foundation as a licensed therapist

Founder and CEO of Delphi, with certification in Psychedelic Therapies and Research (CPTR)

- Major Insurer Roles Anthem Blue Cross (2010-2019)
   As Program Manager for Autism (ASD), developed the strategy for integrating a new, complex behavioral health specialty into one of the largest health insurers in the US

Founder, Delphi

- Gained deep expertise in clinical policy, benefits administration, network development, and payment integrity for novel treatments
- Key Reimbursement Achievements
- Work has directly secured insurance coverage for over 20 million covered lives and indirectly influenced the entire US commercial market
- Successfully designed and launched health insurance products covering psychedelic-assisted therapy

#### Clinical Foundation

- Qualifications & Credentials
  - Licensed Marriage and Family Therapist (LMFT)
  - o Certified in Psychedelic Therapies and Research (CPTR), CIIS
- Clinical Experience
- Over a decade of direct clinical service in diverse settings, including community mental health, crisis counseling, and private practice
- Grounded in a deep understanding of patient needs and the realities of therapeutic practice

# Lia Mix, LMFT, CPTR

linkedin.com/in/liamix/

#### Psychedelic-Specific Experience

Company Founding & Leadership

- Delphi: Founder & CEO, advising leading nonprofits, for-profits, and government bodies on responsible integration of psychedelic therapies
- Enthea: Founder & CEO of the first organization to offer psychedelic-assisted therapy as a workplace benefit covered by health insurance, a landmark achievement in US market access

#### **Ecosystem & Policy Influence**

- Has advised and briefed the U.S. Department of Health and Human Services (HHS) on the spectrum of access pathways for psychedelics
- Founding Advisor to the American Psychedelic Practitioner Association (APPA) and the Psychedelic Bar Association
- Featured speaker at leading conferences such as Horizons

#### Academic & Research Affiliations

- California Institute of Integral Studies (CIIS): Adjunct Faculty and Co-founder of the CPTR Alumni Association
- Psychedelic Research and Training Institute (PRATI): Director on the Board of Directors

# Floris Wolswijk, MSc

Founder, Blossom

Founder of Blossom, Europe's leading psychedelic research intelligence platform

Authored the first pan-European report on reimbursement pathways for psychedelic therapies

Senior PM & EU Lead for Delphi, advising on policy, reimbursement, and health system engagement

Combines data-driven analysis with hands-on experience in psychedelic-assisted coaching

MSc in Industrial & Organisational Psychology from Erasmus University Rotterdam

#### European Market Access & Intelligence

- Blossom Psychedelic Insights Platform
- Built and maintains the most comprehensive open database of psychedelic research (2,200+ papers)
- Publishes a bi-weekly newsletter on psychedelic science and strategy read by over 3,500 professionals
- Co-authored the 200-page "Reimbursement Pathways for Psychedelic Therapies in Europe" report (2025), the foundational analysis for the RIPE initiative
- Delphi European Leadership
- Leads Delphi's European consultancy efforts, with a primary focus on reimbursement strategy, health policy, and system engagement
- Advises non-profits, biotech start-ups, and governments on evidence generation and HTA readiness
- OPEN Foundation ICPR Conference (Volunteer Leadership)
- Organised and advised on key strategic components of the Interdisciplinary Conference on Psychedelic Research (ICPR) across multiple events (2020-2024)
- o Organized the full 'Business Day' for ICPR 2022, convening industry leaders to discuss the future of the field
- Advised on the 'Implementation Day' program for ICPR 2024, focusing on real-world clinical and policy challenges
- Led the digital/tech team for the virtual ICPR 2020

# Floris Wolswijk, MSc

linkedin.com/in/floriswolswijk/

#### U.S. Policy & Strategy Engagement (via Delphi)

High-Level Stakeholder Briefings

- Provided guidance and ecosystem analysis to U.S. government stakeholders, including the Department of Health and Human Services (HHS), on access pathways
- Advised international drug developers on navigating the US market, providing a transatlantic perspective on reimbursement and policy challenges

#### Psychedelic-Assisted Coaching (FLO Coaching)

**Grounded Clinical Application** 

- Provides 1-on-1 psychedelic-assisted coaching sessions using legal psilocybin truffles in the Netherlands
- Applies a structured approach based on Acceptance and Commitment Therapy (ACT) with a focus on preparation, dosing, and integration
- $\bullet \ \, \hbox{Offers a practical, "on-the-ground" understanding of the therapeutic process that informs high-level strategy }$

RIPE mission focus

# Our Strategic Focus is on Bridging a Critical Gap

#### **Drug Developers**

Scope: Myopic & Product-Specific

Primary Goal: Secure regulatory approval for a single therapy.

Method: Internal R&D and regulatory engagement.

Timeline: Short-term (to approval).

Key Risk: Can't build the neutral, system-wide infrastructure needed for access.

#### RIPE

Scope: Targeted & System-Focused

Primary Goal: Achieve reimbursement readiness for all approved therapies.

Method: Deliver fixed, focused projects and open-source tools.

Timeline: Mid-term (1-3 years) for tangible outputs.

Our Value: We build the practical, neutral tools that allow approved drugs to navigate complex laws and reach patients.

## Broad Alliances / Lobbyists

Primary Goal: Long-term legislative change

Scope: Pan-Systemic & Political

Method: General advocacy,

(e.g., rescheduling, HTA modification).

Method: General advocacy, consensus-building, government relations.

Timeline: Long-term (5-10+ years) for policy shifts.

Key Risk: Can be too slow and general to solve near-term, technical reimbursement hurdles.

RIPE mission focus

# What We Do & What We Don't

#### What We DO

Focus on Regulatory-Approved Therapies: Regulatory approval is a milestone, not the finish line. Our mission is to solve the reimbursement hurdles that come next.

Build Tailored Reimbursement Frameworks: We create the specific health economic models and payment pathways needed for payers.

Deliver Fixed, Focused Projects: We produce tangible, time-bound deliverables like toolkits, models, and guides.

Support Equitable Systemic Access: Our ultimate goal is to create pathways that enable fair access for patients within the healthcare system.

#### What We DO NOT DO

Advocate for Rescheduling or Legalisation: This vital work is the focus of other dedicated organisations.

Become a General Lobbying Organisation: Our focus is on technical solutions, not open-ended political advocacy.

Develop or Promote Any Single Therapy: We are neutral, non-commercial, and our work is designed to benefit the entire class of therapies.

Focus on Unregulated or Alternative Access: Our expertise is navigating and preparing the formal, regulated healthcare systems.

Our disciplined focus on a specific set of technical problems is our greatest strength. It ensures we can deliver tangible, high-impact results that benefit the entire ecosystem.