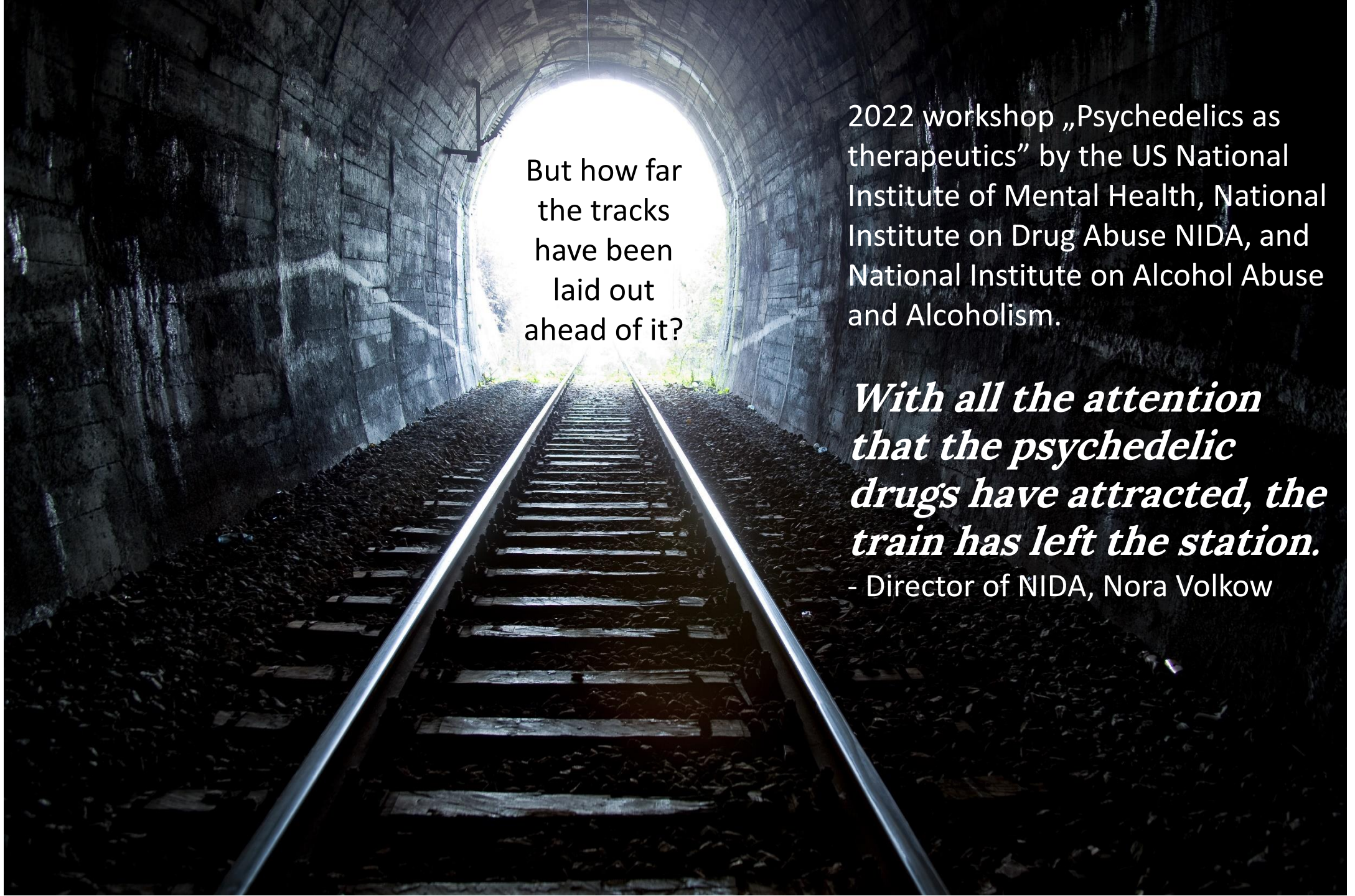
PAREA
PSYCHEDELIC ACCESS AND RESEARCH EUROPEAN ALLIANCE

The inaugural meeting of PAREA members

14 April 2022, 13.00 – 15.00 CEST

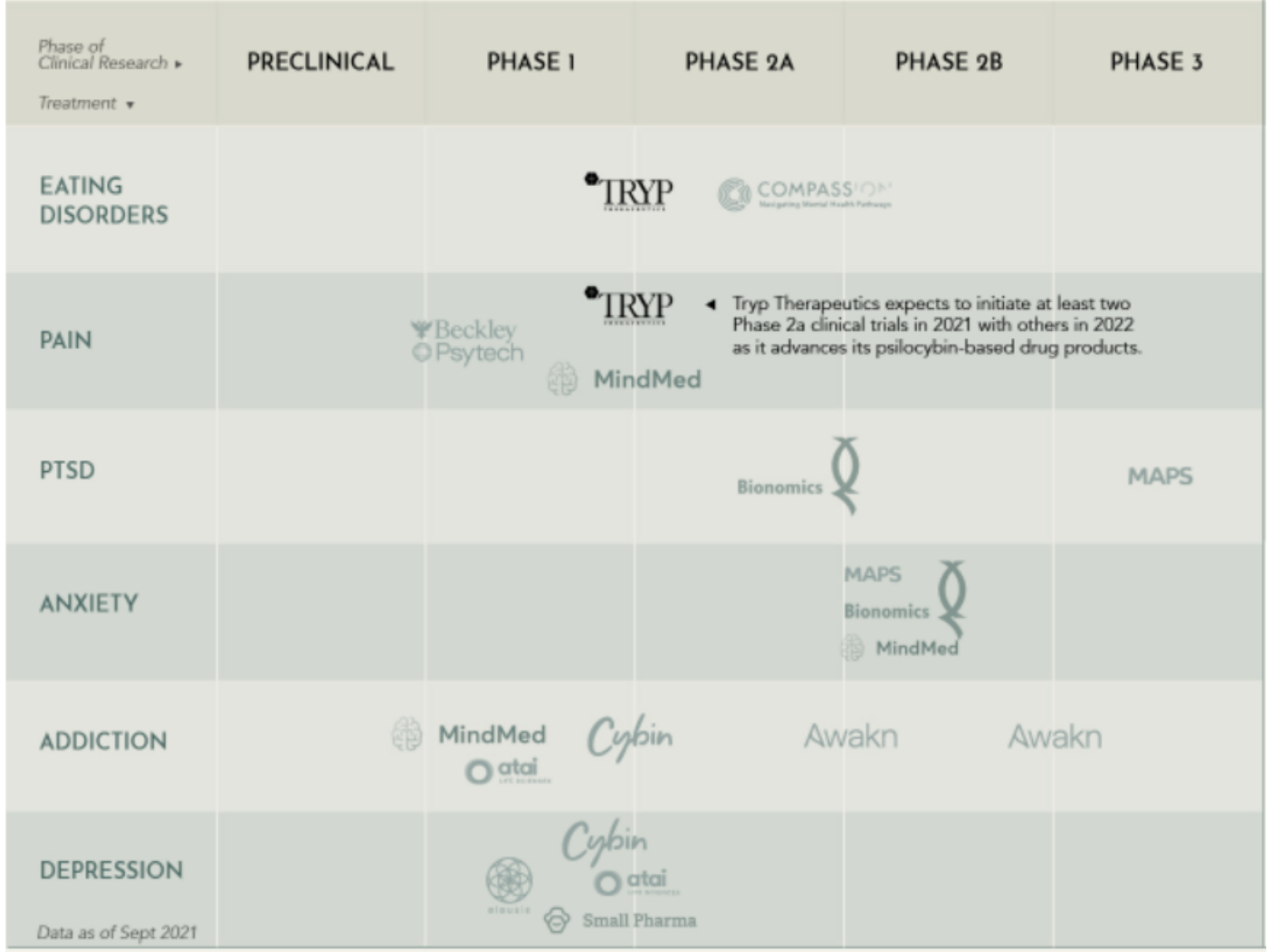


2022 workshop „Psychedelics as therapeutics” by the US National Institute of Mental Health, National Institute on Drug Abuse NIDA, and National Institute on Alcohol Abuse and Alcoholism.

With all the attention that the psychedelic drugs have attracted, the train has left the station.

- Director of NIDA, Nora Volkow

Company	Indication	Phase I	Phase II	Phase III
MAPS	*Post-traumatic stress disorder (PTSD)*	MDMA		III
COMPASS Navigating Mental Health Pathways	*Treatment-resistant depression (TRD)*	COMP360	II	
Usona Institute	*Major depressive disorder (MDD)*	Psilocybin	II	
MAPS	*Eating disorders (anorexia nervosa and binge-eating disorder)*	MDMA	II	
MAPS	*Anxiety associated with a life-threatening illness*	MDMA	II	
MAPS	*Social anxiety in autistic adults*	MDMA	II	
MindMed	*Generalized anxiety disorder*	MM-120 (LSD)	II	



VISUAL CAPITALIST /visualcapitalist @visualcap visualcapitalist.com

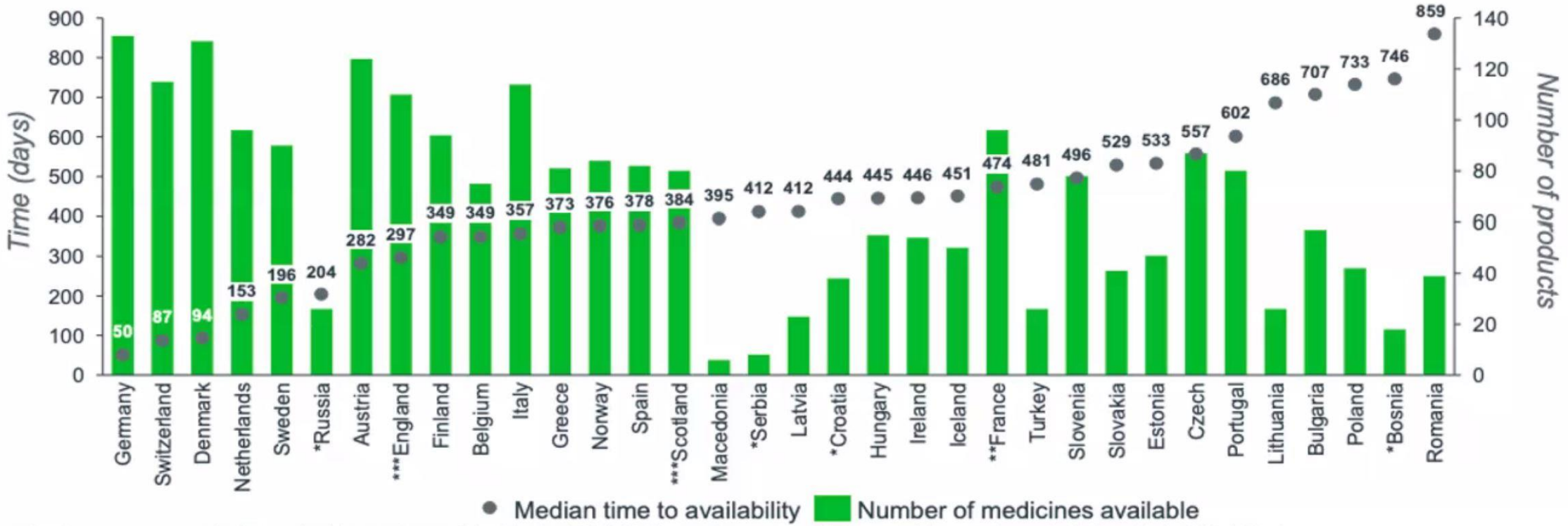
Source: Psilocybin Alpha, Tryp Therapeutics

**Based on companies that exhibit substantial activity in a given segment; not an exhaustive list*

Current situation for access and availability to innovative medicines

Median time to availability (2016 – 2019)

The **time to availability** (previously know as length of delay) is the days between marketing authorisation and the date of availability to patients in European countries (for most this is the point at which products gain access to the reimbursement list †).



†In most countries patient access equates to granting of access to the reimbursement list, except for hospital products in DK, FI, NO, SE some products are not covered by the general reimbursement scheme and so this shorter delay is artificially declining the median and average; *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. **In France, some innovative products without competitors can be made available prior to market authorisation under the system of Temporary Authorisations. As these are not taken into account in the analysis, the average for France would be lower in reality. ***In the UK, MHRA's Early Access to Medicines Scheme provides access prior to marketing authorisation but is not included within this analysis, and would reduce the overall days for a small subset of medicines


REMOVING BARRIERS
TO RESEARCH AND ACCESS


PATIENTS
AFFORDABILITY
ACCESS
RESEARCH

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PAREA GOVERNANCE

Membership

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Full and Founding Members

1. Association of European Cancer Leagues (ECL)
2. Beckley Foundation
3. Drug Science
4. European Brain Council (EBC)
5. European College of Neuropsychopharmacology (ECPN)
6. European Federation of Neurological Associations (EFNA)
7. Global Alliance of Mental Illness Advocacy Networks- Europe (GAMIAN-Europe).
8. OPEN Foundation
9. Osmond Foundation

Observers

International Center for Ethnobotanical Education, Research, and Service (ICEERS)

Industry Partners

- Awakn Life Sciences
- Beckley Psytech
- Cybin
- MindMed

Membership Details: Full members and Observers

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Full Members

- European/global organizations: patient organizations, medical associations, scientific societies, umbrella coalitions, psychedelic charities and foundations
- Support achieving PAREA's objectives and recommendations
- Support the agreed plans and their implementation
- Actively take part in PAREA meetings and activities
- Contribute to the discussion and are invited to express their views
- Are acknowledged on relevant material and documents produced by PAREA
- Participate in the appropriate dissemination of the Alliance's activities
- Provide logo to develop materials recognising the broad range of collaboration
- New members must be approved by PAREA members

Observers

- On special occasions, the partnership can accept an organization as an Observer.

Working with Industry

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- Companies become Industry Partners and are provided with an opportunity to work with the civil society – PAREA full members - at the European level in a transparent and accountable framework
- This happens in open dialogue and clear financial arrangements to ensure that the Partners' support is demonstrated, whilst PAREA's independence as a civil-society led organization is maintained
- For-profit partners shouldn't have any links to harmful commodities industries such as alcohol and tobacco.

Funding

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- Industry partners
- Psychedelic foundations can decide to offer financial support to the Alliance
- More funding will be sought both from for and non-profit actors.
- The sponsorship obtained for the Alliance is used to fund the day to day project management of PAREA including staff time, promotional materials and travel costs incurred for attendance at meetings/events.

Set up, Governance and Decision Making 1

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Legal set up

- Currently, PAREA is not an officially registered entity and is housed within Drug Science which:
  - Provides secretariat to the partnership
  - Is responsible for the financial agreements with PAREA partners and its internal policies and procedures apply

Steering committee

- PAREA is governed through a Steering Committee composed by the Full Members
- Members are invited to delegate 1-2 representatives to sit at the SC (not mandatory)
- SC will meet at least 3 times per year. It will be responsible for the executive strategy of the Alliance. It will operate by consensus
- Although the SC can provide advice/recommendations, Full Members are responsible for the final approval of PAREA's statements, responses to consultations, updates to the strategic direction, etc.

Set up, Governance and Decision Making 2

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Secretariat

- Responsible for the ongoing administration of PAREA, strategic and operational advice, fundraising, representing the Alliance at the external meetings and events, conducting its activities, and any other implementation support by agreement with the members

Biannual meetings

- Twice a year all PAREA members, including Industry Partners, will convene to discuss PAREA's work.

Set up, Governance and Decision Making 3

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PAREA Chairmanship

- Full Members will select a Chair and Vice Chair among its members during the first meeting of PAREA
- Chairs will be appointed for 1 year
- Role of the Chairs is to: lead meetings so that agendas are followed; moderate discussions and allow all members and different points of view to be heard during discussions; be a sounding board for staff in the preparation of agendas and how to best involve the full committee in work plan tasks

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Approval of the terms of reference by Full Members

Elections of Chair and V-Chair

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PSYCHEDELIC-ASSISTED THERAPIES: THE LATEST CLINICAL PROGRESS AND 2022 PROJECTIONS

Prof. David Nutt
Imperial College London
Drug Science

2021 in review

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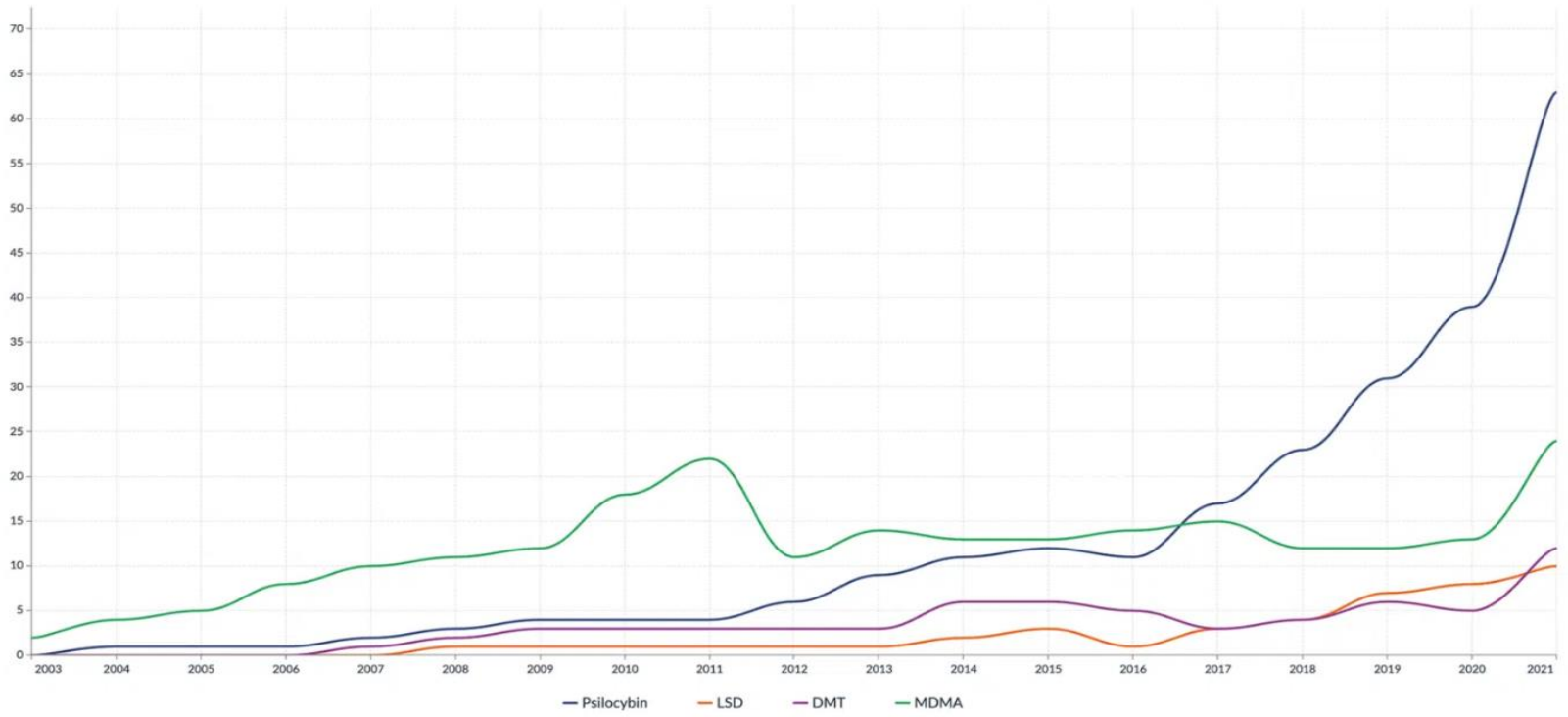
- Dozens of trials and hundreds of studies published in 2021, expanding the depth and scope of scientific inquiry. But ….
  - Lengthy timescales involved in drug development, with clinical trials regularly taking in excess of six years to complete
  - Important to appreciate the methodological challenges inherent in psychedelic research, as well as the broader fields within which such research is nested
- Regulators demonstrating an increasingly positive attitude.

Active Clinical Trials on Different Psychedelics

Data on Psilocybin, LSD, DMT, and MDMA Sourced from Dimensions Analytics



Key Studies in 2021

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- Psilocybin Goes Head-to-Head with SSRI Antidepressant: New England Journal of Medicine
- Multidisciplinary Association for Psychedelic Studies (MAPS) publishes results from Phase 3 Trial of MDMA-Assisted Therapy for PTSD: Nature Medicine

Key Studies in 2021

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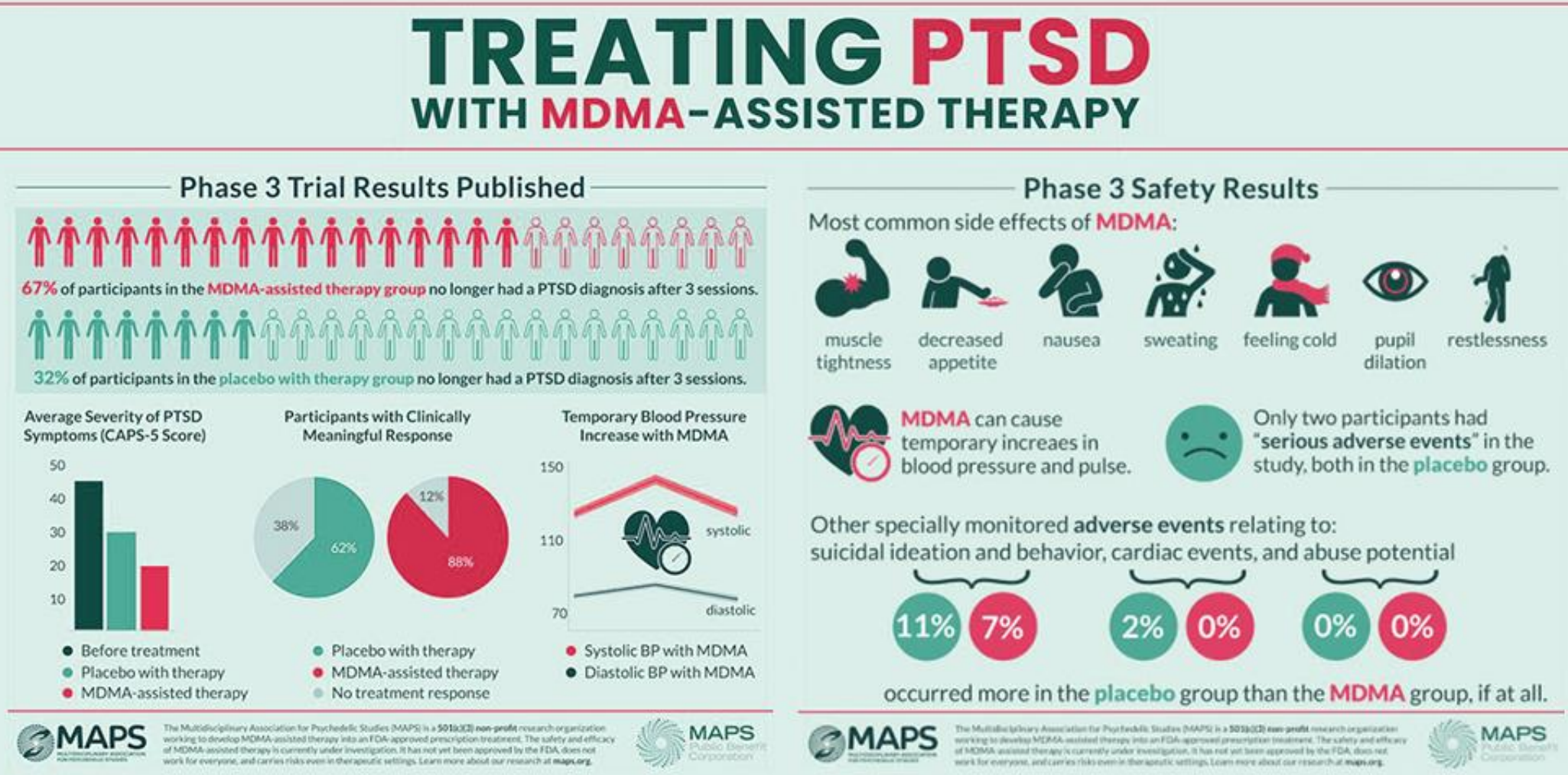
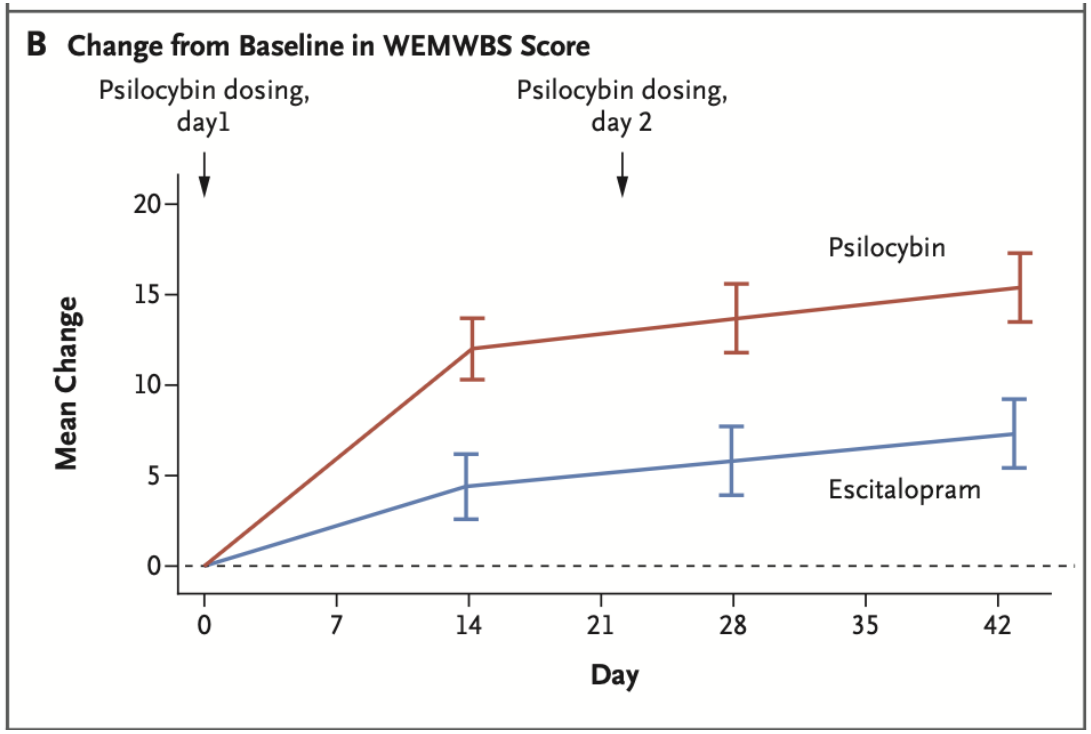
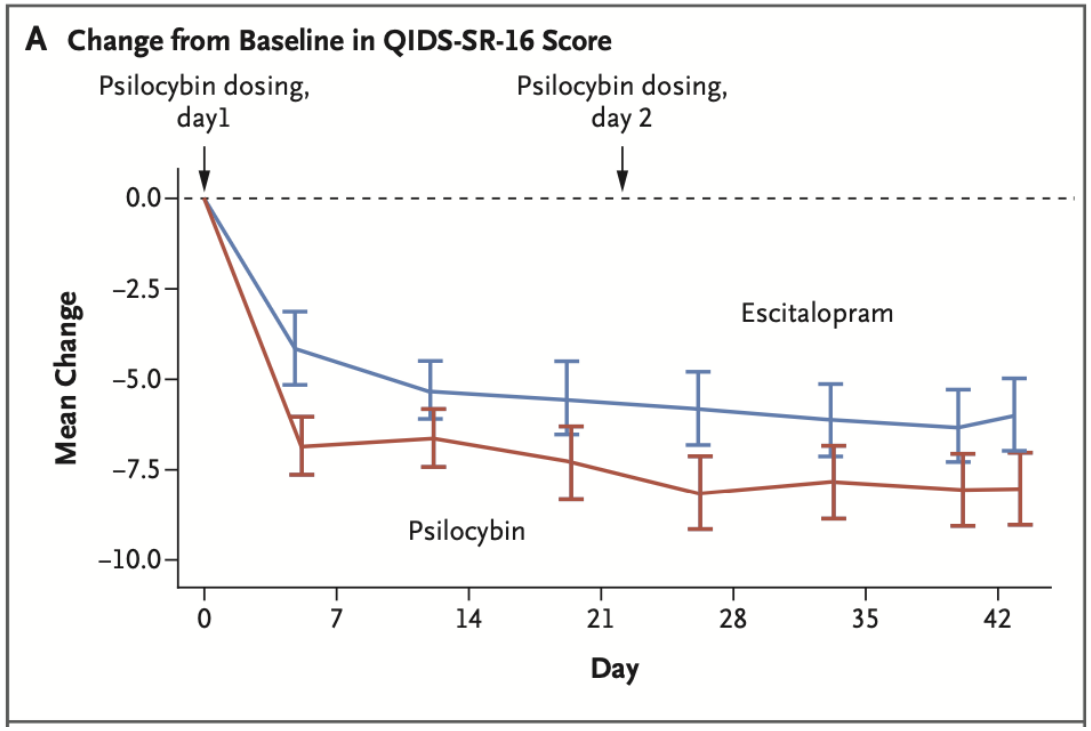
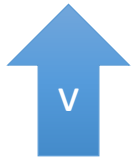


Psilocybin two doses –v- escitalopram







Carhart-Harris et al NEJM 2021

Remission rates much higher with psilocybin

Scale	Psilocybin	Escitalopram
QIDS	57	29
BDI	58	18
HAMD	49	10
MADRS	29	7

Remission rates as % total @ 6 weeks

Another trials with psilocybin in depression

Johns Hopkins – comparison with no-treatment ➔

Figure 3. Comparison of GRID Hamilton Depression Rating Scale (GRID-HAMD) Scores Between the Delayed Treatment and Immediate Treatment Groups

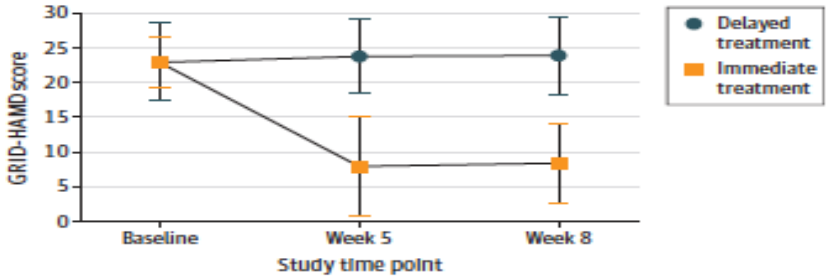
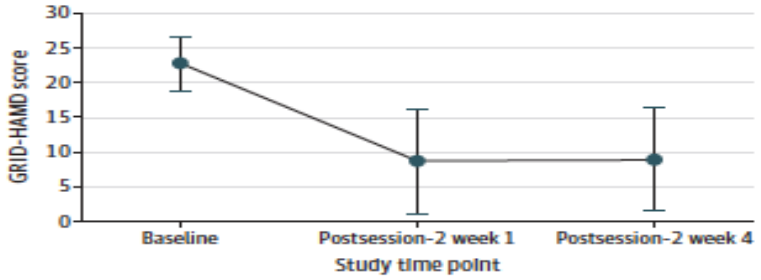
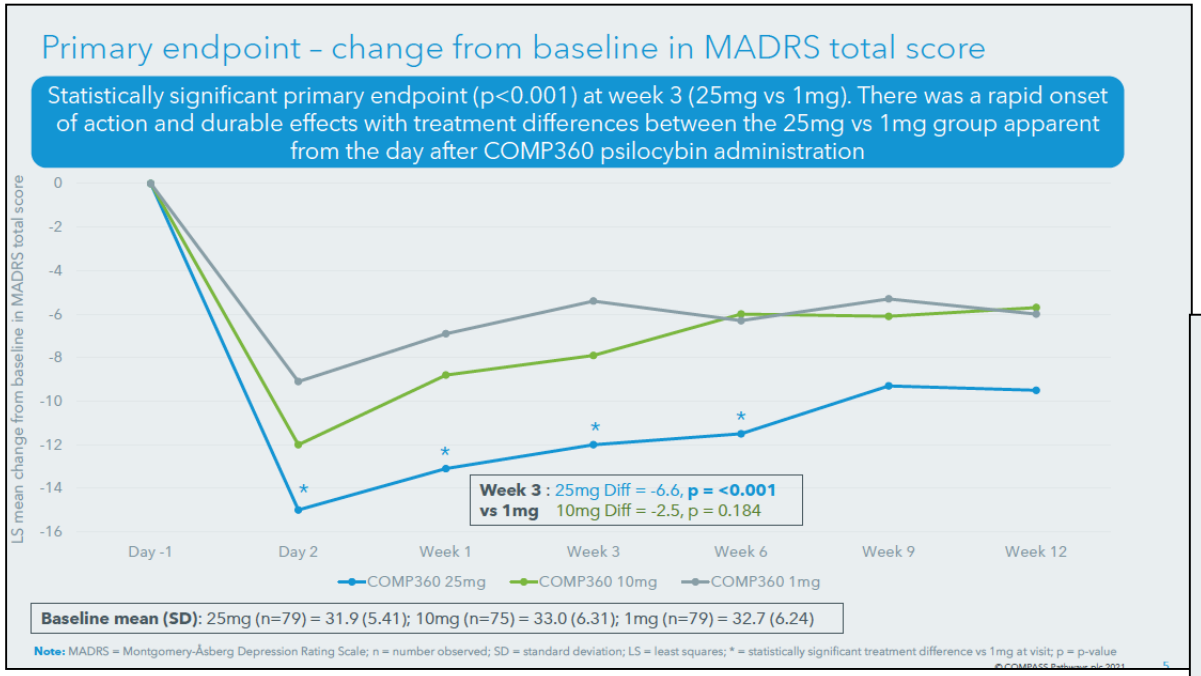


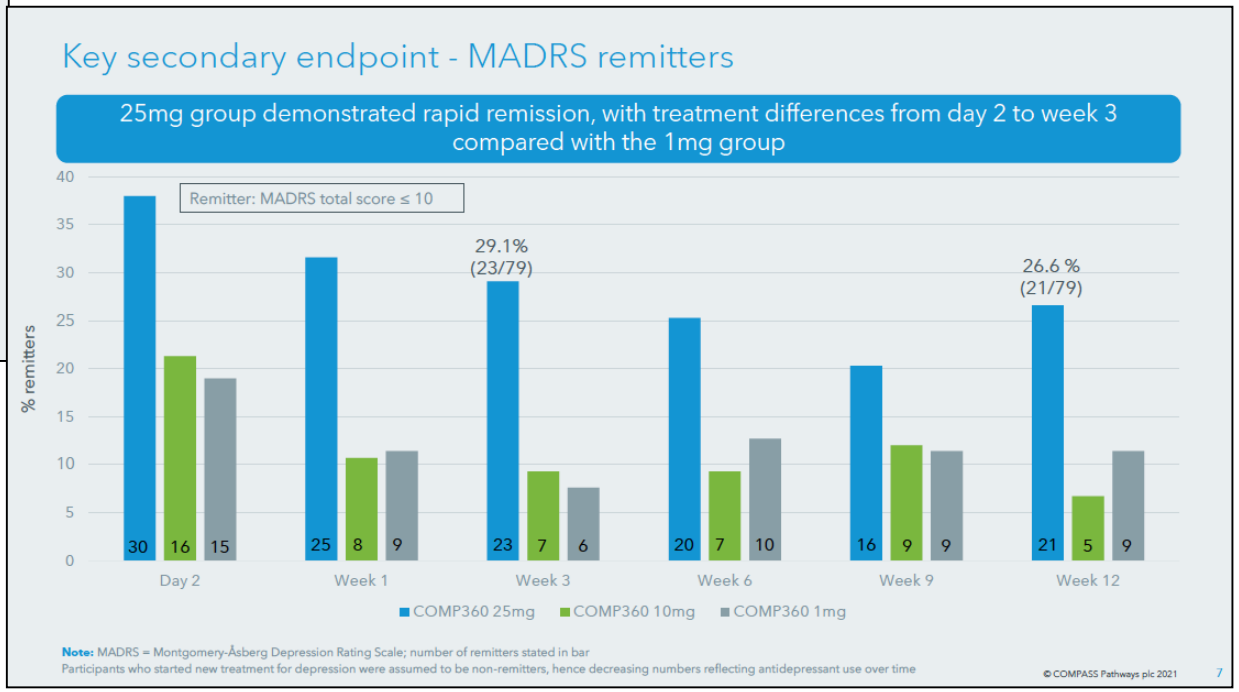
Figure 4. Decrease in the GRID Hamilton Depression Rating Scale (GRID-HAMD) Scores at Week 1 and Week 4 Postsession-2 Follow-up in the Overall Treatment Sample

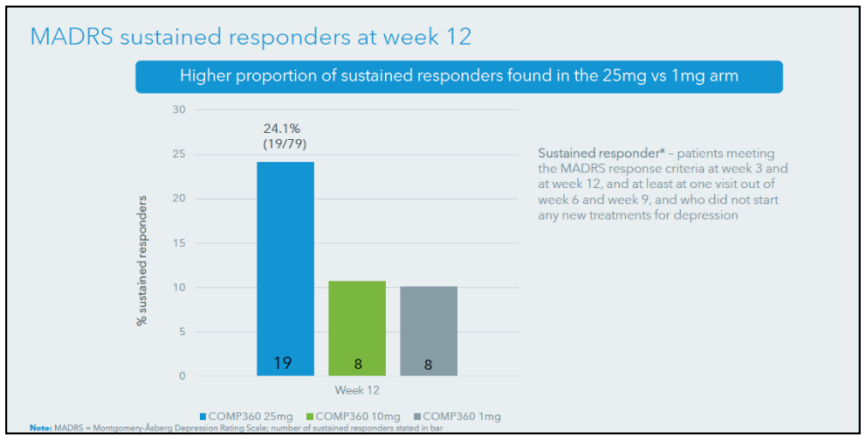


Davis et al 2021 JAMA Psychiatry

COMPASS Pathways new trial (not yet published)







Key Studies in 2021

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- Psilocybin Goes Head-to-Head with SSRI Antidepressant: New England Journal of Medicine
- MAPS Publishes Results From Phase 3 Trial of MDMA-Assisted Therapy for PTSD: Nature Medicine
- Psilocybin for Treatment-Resistant Depression: COMPASS Pathways' Phase 2b Results (unpublished)
- Studies looking at the effect of psychedelics on neuroplasticity & neurogenesis: an expansion of indications to investigate neurological conditions
- Studying interactions between SSRIs and psilocybin.

Regulatory Advancements in 2021

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- Biden-Harris Administration Recommends Reducing Barriers to Research For Schedule I Substances
- Federal Grant Awarded to Johns Hopkins Researchers to Study Psilocybin for Smoking Cessation
- US National Institute on Drug Abuse Partners with Psychedelics Companies
- DMT Therapy Receives Fast-Track Designation in the UK
- Harvard Law School's Petrie-Flom Centre Launches Research Initiative on Psychedelics and the Law

2022 Predictions and Trends

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- Psychedelics R&D moving beyond mental health: more investigations geared toward treating a broader set of conditions such as neurological disorders and pain-related indications.

An Overview of Target Indications for Psychedelics

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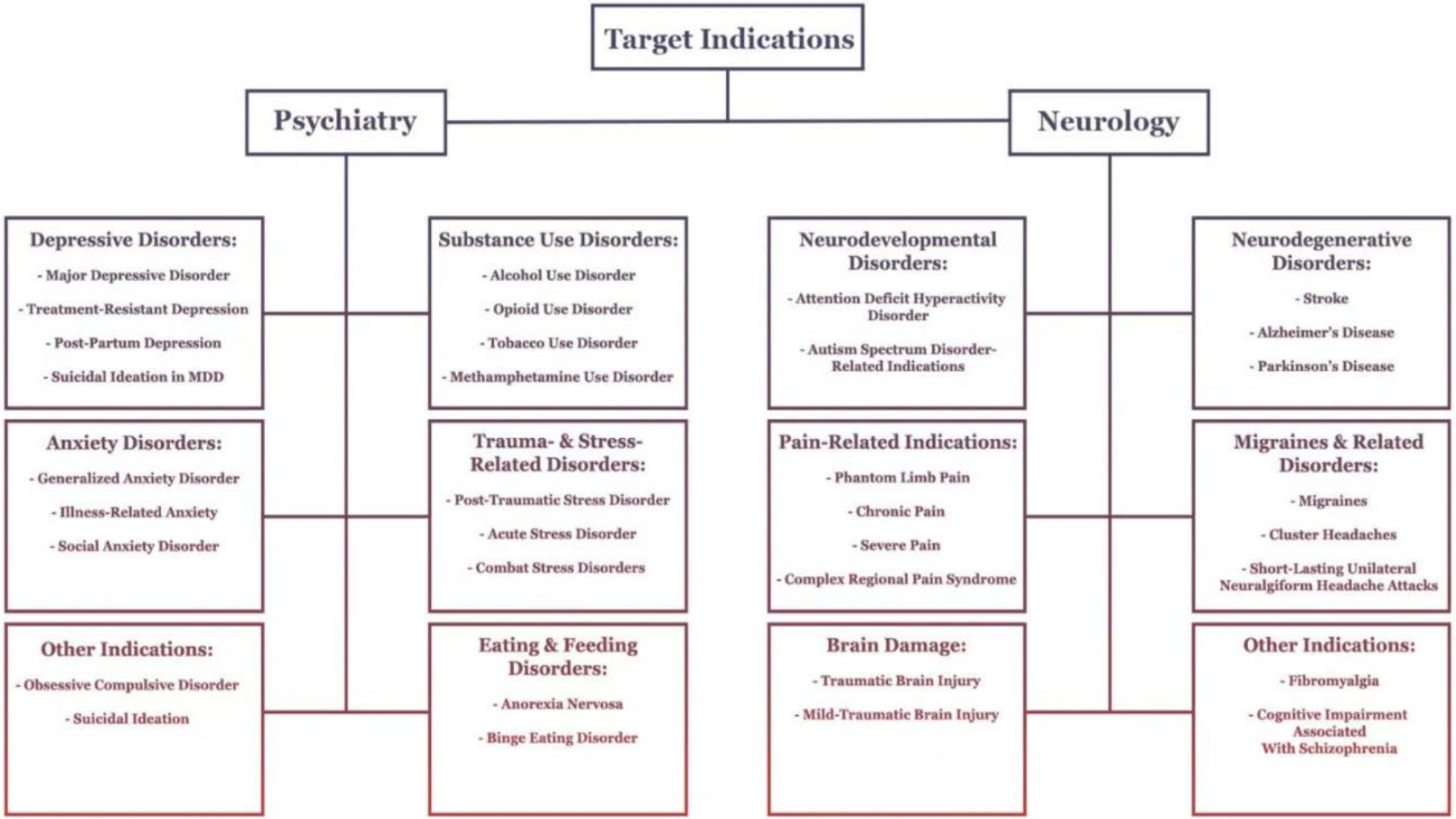

2022 Predictions and Trends

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- Psychedelics R&D moving beyond mental health: more investigations geared toward treating a broader set of conditions such as neurological disorders and pain-related indications
- Insurance coverage early negotiations: As MAPS' MDMA-AT for PTSD nears potential approvals, and COMPASS Pathways enters Phase 3 trials, a greater focus on the cost-effectiveness of psychedelic-assisted therapies and the willingness of insurance companies to cover these novel treatments
- Oregon Psilocybin Services model

Major Trials Finishing/Beginning in 2022

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- MAPS | Phase 3 (#2) | MDMA-AT for PTSD: expected to conclude in November. If results are statistically significant, and no novel safety issues emerge, MAPS will finalise its New Drug Application with the FDA
    - Following a recent fast-track designation from UK regulators. "MAPS will also seek to broaden its footprint geographically, including training of about 40 therapists in 6 countries and 9 sites in England and Europe who will be conducting Phase 3 research into MDMA-assisted therapy for PTSD
- COMPASS Pathways | Phase 3 | COMP360 Psilocybin for TRD: the first for-profit company to take a classic psychedelic into a Phase 3 trial
- And – hot off the press (11 April) - Nature Medicine : „Increased global integration in the brain after psilocybin therapy for depression"

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POLICY OBJECTIVES AND UPCOMING ACTIVITIES

Context

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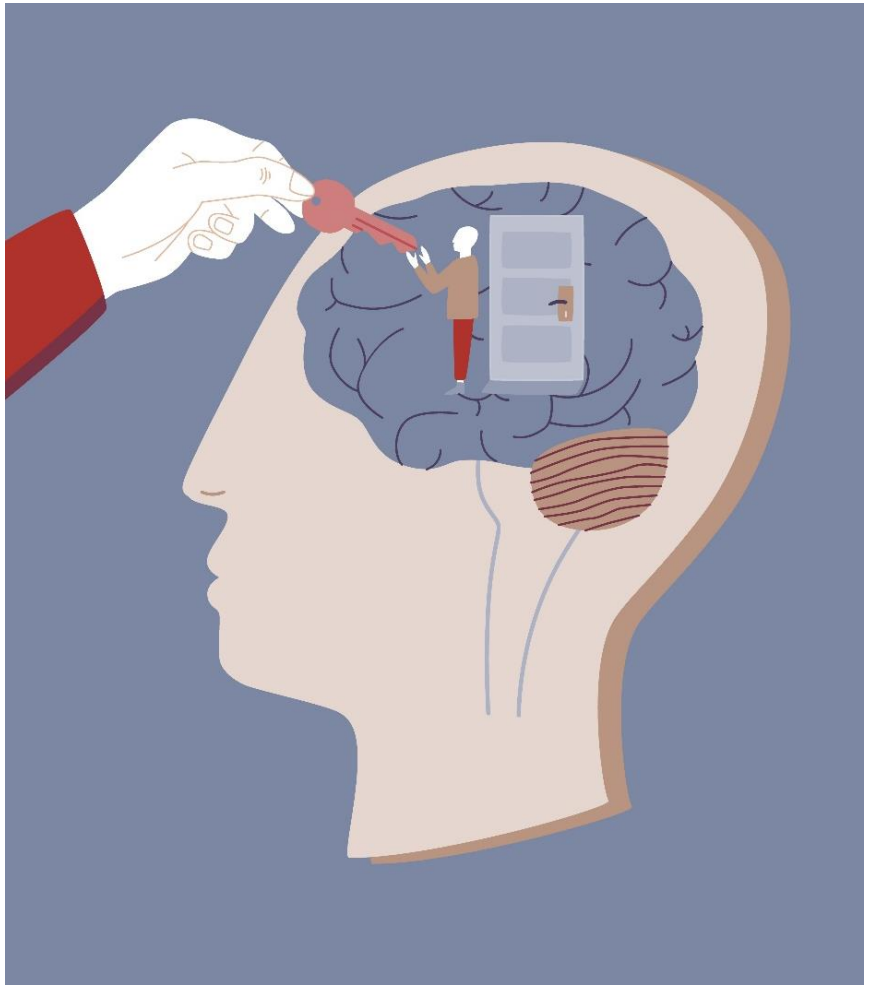

- Mental health and mental healthcare crisis; innovation challenges in brain research
- Groundbreaking scientific advances related to psychedelic drug development and therapeutic use → lead to regulatory approvals around the world, including in Europe
- Those developments need to be complemented by a prior engagement with the European Institutions and EU regulators
- Ensure that necessary European infrastructure and competencies are developed in advance.

Mission

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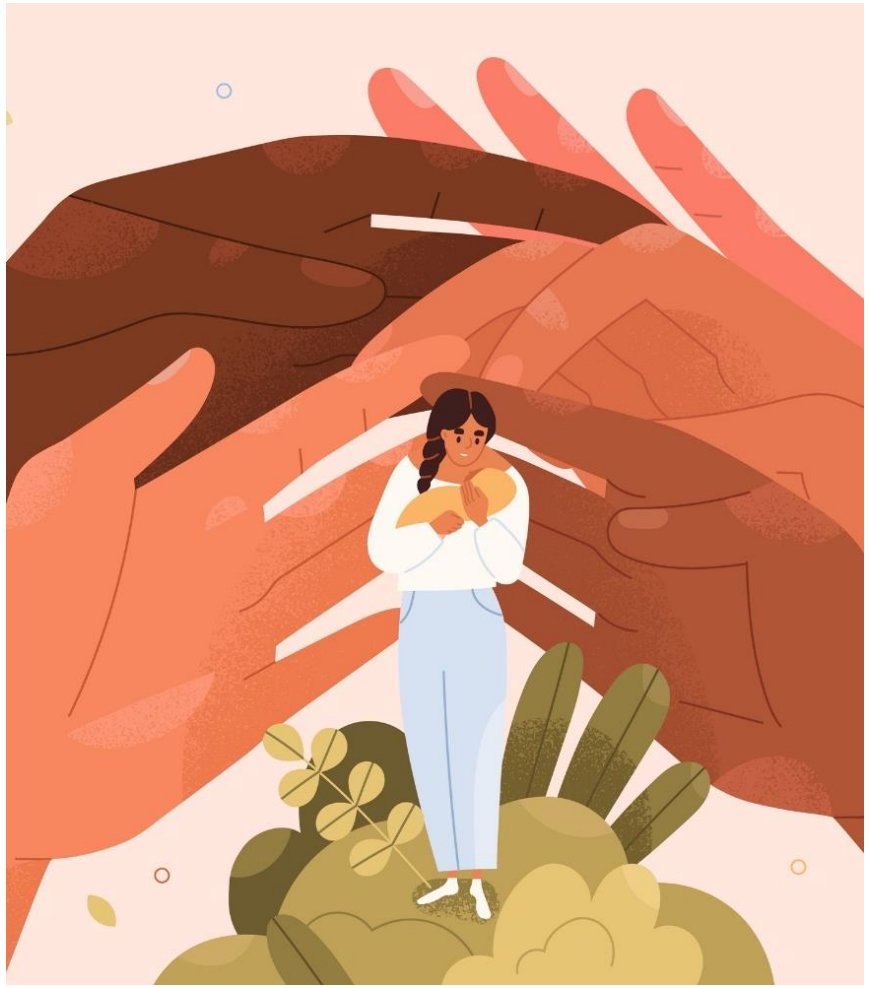

Modern, rational, and ethically responsible integration of psychedelic-assisted therapies into European mainstream mental health services, where those novel treatments are an additional therapeutic option, accessible and affordable for all, as registered and reimbursed medical treatments.

Vision

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A world in which **brain health is valued**, preventable **suffering is avoided**, and **psychedelic novel treatments help people** to heal and enhance their sense of wellbeing.

Objectives

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Foster research to increase clinical evidence supporting the safe use of psychedelic compounds as therapies, and ease the barriers to doing research with these compounds

Decrease stigma by education and promoting evidence-based information and debunking myths

Promote meaningful patient engagement across all development phases of novel psychedelic medicines and accompanying psychotherapeutic treatment practice

Increase collaboration between civil society, scientists and policymakers

Build capacity at the healthcare-systems level by identifying bottlenecks and capacity constraints to deliver at scale and by ensuring that necessary European infrastructure and competencies are developed in advance

Ensure equitable, timely, affordable, and legal access to safe and effective psychedelic-assisted treatments when they become available

Support drug reform to promote health-oriented, harm-reducing drug policies based on scientific evidence and human rights

Contribute to a diverse and equitable psychedelic ecosystem taking into account issues such as sustainability, reciprocity, diversity, fair IP management, open science as well as ethical and constructive business models.

PAREA Pillars

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REPRESENTATION

Non-profit, membership-led, multistakeholder and multidisciplinary partnership. We bring together patient organizations, medical associations, scientific societies, umbrella coalitions, psychedelic foundations, and for-profit sector.

RECOGNITION

Science-driven and evidence-based education to address stigma and make the potential of psychedelic-assisted therapies understood among EU policy-makers.

POLICY & ADVOCACY

- Build EU-specific agenda taking into account members' common areas and goals
- Develop a policy action plan targeting EU institutions and relevant policy files
- Map out relevant EU policy initiatives and understand systemic barriers and policy opportunities which must be addressed

Horizontal EU policy hooks

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Leverage relevant EU public health priorities

EU is governing the bulk of its health policies in the frame of non-communicable diseases (NCDs). This includes Europe's Beating Cancer Plan and EU mental health policies

EU4Health Programme (€5.1 billion): funding to EU countries, NGOs and health organisations. EU NCD Initative will be central

EU Pharma Strategy

EU NCDs portfolio rooted in Sustainable Development Goals. Of particular relevance are goals related to decreasing the mortality from NCDs and mental health (SDG 3.4), including Suicide Mortality Rate (indicator SDG 3.4.2)

R&I programme Horizon Europe (€95.5 billion), including Innovative Health Initiative and partnership on brain research (as of 2025).

COVID and refugee crises aggravate further mental health problems

Policy and Advocacy: Building Relationships

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Engagement with relevant European Commission bodies:
DG SANTE | DG Research | EMA | European Monitoring Centre for Drugs and Drug Addiction) | DG CONNECT | DG Home | Civil Society Forum on Drugs (EC Expert Group)

EU Health Policy Platform
- General engagement - interface between civil society and the EC and member states
- Thematic networks can be set up

Engagement with relevant European Parliament bodies and Members of the EP (MEPs)
- ENVI (health) and ITRE (research) committees
- European Parliament hosts informal interest groups and alliances: build an alliance of Members of the EP

WHO Europe
- Mental Health Coalition
- NCD Advisory Council

Wider EU health and reseach ecosystem
- Participate in relevant meetings
- Join and cooperate with informal alliances of EU public health groups, e.g. EU Health Alliance, EU4Health Civil Society Alliance and Mental Health Advocacy Platform

Stakeholders Mapping

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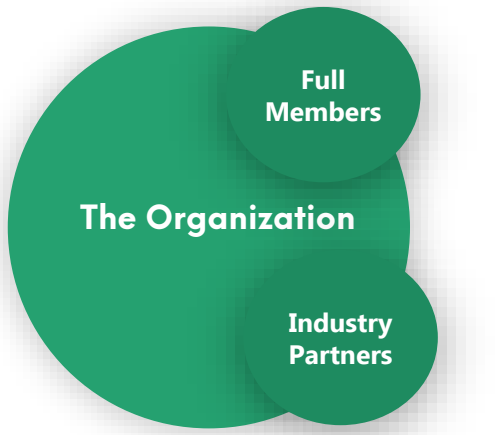

Stakeholders Mapping

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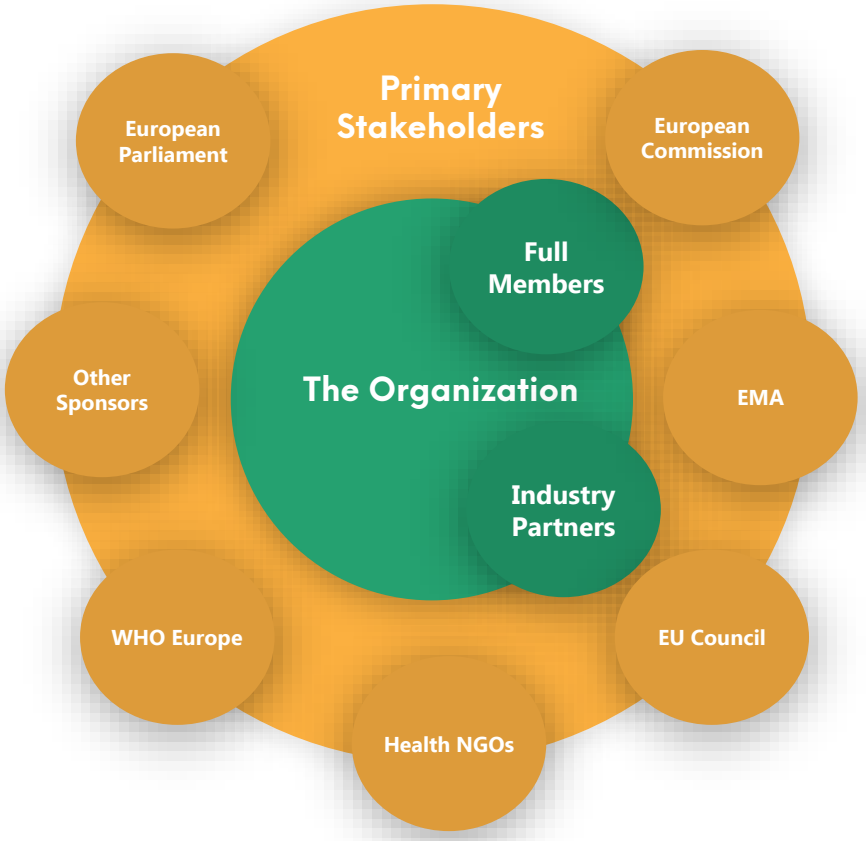

Stakeholders Mapping

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Plans for 2022

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- **Meetings**
- Launch event: early June (TBC, virtual)
- Held a meeting in the EP in the fall
- Participate in the Brain Innovation Days (11-12 October)

- **Policy recommendations**
- Call to action
- Detailed policy recommendations

- **European Parliament**
- Set up a coalition of supporters

- **Consultations**
- Joint Statement on an inclusive Pharmaceutical Strategy (15 April)
- Shared European Brain Research Agenda (SEBRA) (until 30 Aprill)
- NCD Initiative (until 30 April)

Plans for 2022

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Media

Publish a though-leader piece accompanied by an article by an MEP in the Parliament Magazine

Enage with POLITICO and other relevant media outlets

MENTAL HEALTH

Recognising the challenges, adopting exceptional measures

The EU must find more innovative ways for its policies to have an impact on mental health, says **Adina Vălean**

Adina Vălean (EPP,RO) is chair of the European Parliament's Environment, Public Health and Food Safety (ENVI) Committee

Nowadays, public health challenges are more and more complex and interlinked, which drives us to take a strategic approach to addressing them at all levels – individual, institutional, community, local or national. Coordinated initiatives are needed in order to integrate and ensure coherence between the many different sectorial policies, which are relevant to keeping individuals and populations healthy. This also applies to the field of brain disorders that, according to the WHO, account for 35 per cent of the burden of all diseases in Europe and are predicted to become the major medical need of the 21st century. Many of the most prevalent brain disorders are chronic diseases that affect patients over a long period of time and generally progress slowly. Among the different chronic diseases, mental health is a real public health challenge; an estimated 18.7 million EU citizens are expected to live with dementia by 2050. Depression and anxiety are yet other examples of highly prevalent and disabling conditions - each year, 25 per cent of the European population suffer from depression or anxiety, up to 50 per cent of chronic sick leave is due to depression or anxiety and half of depression cases are untreated.

Recognising these challenges, the European Brain Council has recently published a study on the value of treatment. I had the pleasure of attending the launch conference where experts involved in the study highlighted the need for more investment into research on neurological and mental diseases and exposed the wide disparities between and within countries relating to detection, intervention and treatment. As Chair of the European Parliament's ENVI committee, I was particularly pleased to see that the findings emphasised the importance of early intervention and detection, which I find essential to reducing the burden on our healthcare systems. It has been well established that timely intervention brings measurable health gains such as improved survival rates, reduced complications and disability, better quality of life and lower treatment costs.

"Each year, 25 per cent of the European population suffer from depression or anxiety, up to 50 per cent of chronic sick leave is due to depression or anxiety and half of depression cases are untreated"

There is a growing body of research demonstrating the impact of integrated care that treats both the brain and the body. Simultaneously treating behavioural and physical conditions leads to better control of depression, diabetes, and heart disease, and importantly contributes to reducing healthcare costs.

Psychiatric illness increases with patients that live with chronic medical illnesses and conversely, these chronic medical illnesses also increase in patients with psychiatric illnesses, particularly in those with major mental illnesses. Consequently, patients with these conditions have increased morbidity and mortality and managing their condition becomes particularly costly at societal level. But because of the way our service systems have evolved over time, the prevailing tendency has been to treat medical and psychiatric illnesses as if they occur in different domains. We now know that this is not true from a patient standpoint, and if we are going to have patient-centred care, it needs to encompass all of the needs encompassed within the patient's journey.

These challenges call for adopting exceptional measures and this brings to my mind recommendations from the High Level Group on maximising the impact of EU Research and Innovation Programmes, led by former WTO Director-General Pascal Lamy. The recommendations focus on maximising the impact of future EU research and innovation programmes and call for adopting a mission-orientated approach to addressing global challenges. I was pleased to see that the aim to "understand and enhance the brain by 2030" is listed in the report as a potential health mission for the post-2020 EU Framework Programme for Research. We, in the European Parliament, support all actors from the EU Institutions, individual MEPs, and industry to further strengthen cooperation between member states and innovation through recommendations, guidelines, workshops, and the exchange of best practices, with the goal of improving the lives of patients affected by neurological brain disorders. I endorse this idea that we should find innovative and comprehensive ways with which policy can successfully contribute in preventing, treating and curing brain-related conditions.

"We should find innovative and comprehensive ways with which policy can successfully contribute in preventing, treating and curing brain-related conditions"

While the goal is very ambitious, striving to understand the brain better and to be able to offer effective treatments for brain disorders is indeed a great gift that we can offer to future generations. It will also have positive implications on the EU's capacity to innovate and on economic growth which requires healthy brainpower.★

This Thought Leader is sponsored by European Brain Council

EARLY DETECTION AND INTEGRATED HEALTH CARE ARE KEY TO TACKLING BRAIN DISORDERS, ARGUES DAVID NUTT

THE PARLIAMENT MAGAZINE'S
THOUGHT LEADER

Imagine not being able to talk because your speech centres have been affected by a stroke. Or not being able to feed yourself because your arms are too weak due to Motor Neurone Disease. Or not remembering the names of your grandchildren because of advancing Alzheimer's disease. These are confronting thoughts, but they are also the very real challenges that are faced by millions of Europeans living with a brain condition – mental and neurological alike.

"We must take action to develop an EU-wide research and public health combined Brain Strategy"

Highly prevalent and disabling, brain disorders today will affect more than one in three Europeans during their lifetime. The European Brain Council (EBC) has been working for the past 15 years to reduce the burden of brain and mental ill health through our project work and studies, generating and supporting evidence based approaches.

One of them is the EBC milestone study on the "Value of Treatment for Brain Disorders" (VoT), published in June. In the past, healthcare systems were primarily hospital-focused. Considering the causes, effects and co-occurrence of chronic conditions as well as current health reforms, health systems transformation towards a more holistic and patient-centred care approach is underway in Europe. The VoT study looked at how to address this by adapting care pathways to the needs of the patient rather than those of the system. We have done this through case study data analysis covering a wide range of neurological and psychiatric disorders. These disorders are complex and interlinked conditions that have a great number of common denominators and challenges. This is why it is essential to manage them in a more seamless and coordinated manner, as opposed to viewing them through separate medical 'silos'. The study identified the major unmet needs and causes for treatment gaps and examined health gains and the socio-economic impact resulting from best health interventions.

Our findings recommend prevention, early detection and integrated health care interventions. They also recommend more research to understand the causes of brain disorders. We must take action to develop an EU-wide research and public health combined Brain Strategy. And we must make the best use of existing resources and establish a European Brain Research Area that can address brain and mental health in a comprehensive and collaborative way. This should, in turn, feed into national efforts and result in the development of National Brain Plans, mirroring successful national strategies in other areas such as cancer or diabetes. We are already devising the next phase of the study that will see the enlargement of its scope but most importantly, we are rolling out the study's recommendations at the national level. We invite you to visit the VoT page where you will find more information and we encourage you to partner with us in implementing its results braincouncil.eu/vot

"Brain disorders today will affect more than one in three Europeans during their lifetime"

David Nutt is president of the European Brain Council