

**PAREA position paper concerning the Horizon Europe 2025 - 2027 Strategic Plan; Selected research priorities in the area of psychedelic science.**

- Further research is needed to generate optimal and robust evidence on the efficacy and safety of psychedelic drugs for brain disorders, including the effects of repeated exposure and potential interactions with existing treatments. As such, public funding is eminently needed for larger, high-quality, long-term independent efficacy trials with rigorous designs, recruiting more inclusively patient populations in whom these drugs are likely to be used if they are approved for clinical use.
- Research on health economics has to follow. Among priority areas for economic analyses are cost-effectiveness and cost-benefit analyses to assess value for money to payers and society at large; scale-up models capturing the cumulative impact of access to psychedelic therapies; and price and market analyses that health care providers and payers will need to plan the delivery of care.
- Funding is needed to research additional less common conditions and therapy modalities that might not be of commercial interest to the pharmaceutical industry.
- There is a need to develop evidence-based protocols to train therapists and build the patient access infrastructure to meet the existing need.
- Mechanistic studies should be pursued to shed more light on biological underpinnings and psychotherapeutic processes responsible for the therapeutic effects of psychedelics. Such studies can help to refine treatment approaches and achieve better target engagement.
- Though from historical data we know the likelihood is low, we need new data documenting the potential risks for harms and to support people with challenging experiences on psychedelics used in the clinical setting. These investigations must be supported by public money.
- From a fundamental neuroscience perspective, there is a need to elucidate what happens at molecular, cellular and network levels. The improved understanding could be used to develop better, safer or more accessible substances or treatments. Moreover, uncovering the mechanisms of psychedelic drugs may show who exactly these drugs can help and in what contexts. Understanding the mechanisms of psychedelic drugs is also important for identifying new therapeutic targets that could preserve therapeutic effects while minimizing undesired side effects.
- Societal impact of psychedelic therapies should be better understood - there is a need to outline policies and ethical guidelines for psychedelic research, examine legal implications of psychedelic use for medical care, and measure psychosocial impacts of psychedelic research. Researching impact on society will require a multidisciplinary team of experts in bioethics, social science, medicine, health policy and law.
- Mental health exists on a complex continuum, with experiences ranging from an optimal state of well-being to states of great suffering and emotional pain. As such, it is not just defined by the presence or absence of mental disorder. Therefore, in addition to the use of psychedelics in medical settings, studies should be conducted on the impact of psychedelic substances on broadly defined spirituality and well-being in healthy volunteers. In the years and decades to come, supporting the safe and appropriate use of psychedelics.