

MAPS is Granted Innovation Passport in United Kingdom for MDMA as an Adjunct to Therapy for PTSD

FOR IMMEDIATE RELEASE

- MDMA as an adjunct to therapy for PTSD is the forty-first treatment to receive the Innovation Passport since its inception in January 2021
- The designation is intended to accelerate the timeline for approval of innovative medicines for treatment of life-threatening conditions or those which present a significant patient or public health need
- MAPS Public Benefit Corporation will coordinate trial design with Medicines and Healthcare products Regulatory Agency to create a road map for early patient access in the UK

The Innovative Licensing and Access Pathway (ILAP) Innovation Passport has been granted to [MDMA as an adjunct to therapy for posttraumatic stress disorder \(PTSD\)](https://maps.org/research/mdma) < <https://maps.org/research/mdma>> in the United Kingdom (UK). The ILAP designation, authorized by a steering group of representatives from Medicines and Healthcare products Regulatory Agency (MHRA), National Health Services of England and Scotland, National Institute for Health and Care Excellence, Scottish Medicines Consortium, and representatives from the ILAP Patient and Public Reference Group, acknowledges that this treatment may have unique potential as a safe and effective treatment for PTSD, a widespread and devastating mental health condition with few successful treatment options.

The Innovation Passport does not reduce the burden of demonstrating that a treatment may be safe and effective, but does provide research organizers with expert advice, patient input, and collaboration throughout the clinical trial design and development process through a product-specific Target Development Profile.

“This innovative approach to innovative treatments aligns key regulatory and healthcare systems across the UK to ensure all of the stakeholders who will be involved in making a treatment accessible are represented. Our promising [Phase 3 results](https://www.nature.com/articles/s41591-021-01336-3) < <https://www.nature.com/articles/s41591-021-01336-3>> lead us to apply for the Innovation Passport. The ILAP Innovation Passport will ensure MDMA as an adjunct to therapy can be made widely available, as rapidly as possible, for the UK PTSD patients who need it.

[Berra Yazar-Klosinski, Ph.D.](https://mapspublicbenefit.com/staff/berra-yazar-klosinski-ph-d/) < <https://mapspublicbenefit.com/staff/berra-yazar-klosinski-ph-d/>>, Chief Scientific Officer at MAPS PBC

MDMA, administered as an adjunct to-trauma-focused therapy for PTSD, is an innovative therapeutic modality currently being investigated through trials sponsored by the nonprofit [Multidisciplinary Association for Psychedelic Studies](https://maps.org/) < <https://maps.org/>> (MAPS) and its wholly owned subsidiary [MAPS Europe B.V.](https://mapseurope.eu/) < <https://mapseurope.eu/>> with support from [MAPS Public Benefit Corporation](https://mapspublicbenefit.com/) < <https://mapspublicbenefit.com/>> (MAPS PBC). Preparatory and integration therapy sessions are combined with three MDMA sessions, spaced a month or more apart, administered by [specially trained clinicians](https://mapspublicbenefit.com/training/) < <https://mapspublicbenefit.com/training/>>. The treatment takes up to three months to complete, and does not require ongoing medication. In a recently completed [Phase 3 trial](https://maps.org/news/media/maps-phase-3-trial-of-mdma-assisted-therapy-for-ptsd-achieves-successful-results-for-patients-with-severe-chronic-ptsd/) < <https://maps.org/news/media/maps-phase-3-trial-of-mdma-assisted-therapy-for-ptsd-achieves-successful-results-for-patients-with-severe-chronic-ptsd/>> conducted in the United States, Canada, and Israel, 88% of participants who received MDMA experienced a clinically significant reduction in symptoms and 67% no longer qualified for a PTSD diagnosis.

“In the last two years, we have all lost so much—an experience reflected in increasing rates of symptoms of serious mental health conditions. For many people who live with PTSD, an already-urgent need has been exacerbated by strains on healthcare systems, isolation, and loss of a sense of security. Despite the profoundly devastating effects of PTSD, few effective treatments are available. We commend the MHRA for recognizing the seriousness of PTSD, a life-threatening condition with a profoundly unmet public health need, and the potential of MDMA-assisted therapy to be part of the solution.

Corine de Boer, M.D., Ph.D. < <https://mapspublicbenefit.com/staff/corine-de-boer-m-d-ph-d/> >, Chief Medical Officer at MAPS PBC

While commonly associated with traumatic events in combat or other military service, PTSD may also be initiated by abuse, neglect, accidents or natural disasters, significant loss, or other difficult experiences. It is estimated that, in 2015, **3% of people in the UK** < <https://academic.oup.com/bmb/article/114/1/147/246250> > were living with PTSD. Common symptoms of the condition include hypervigilance, insomnia, intense feelings of guilt or shame, apathy, and avoidance responses which can exacerbate isolation. Left untreated, these symptoms can cause an increase in susceptibility to mood, anxiety, and substance use disorders; suicidal ideation or attempts; autoimmune disorders such as arthritis and asthma; congestive heart disease and hypertension; ulcers; and epilepsy or neurologic disorders.

MDMA releases oxytocin, vasopressin, and prolactin, neurohormones linked with trust and bonding, and decreases activity in the amygdala, the region of the brain corresponding with fear and traumatic memories. These unique effects are thought to contribute to MDMA's effectiveness as a catalyst to therapy for people living with PTSD. No drug is without risks, so clinical trials have included careful investigation of possible adverse effects. Thus far, no serious unexpected safety signals have emerged and side effects have been found to be temporary and manageable in a clinical setting.

NOTE

The safety and efficacy of MDMA as an adjunct to therapy is currently under investigation. It has not yet been approved by the MHRA, does not work for everyone, and carries risks even in therapeutic settings. These statements are no guarantee of future MHRA approval or availability of MDMA as an adjunct to therapy. These statements necessarily involve known and unknown risks and uncertainties, which may cause actual outcomes to differ materially from our projections.

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ABOUT [MAPS](http://maps.org) < <http://maps.org> >

Founded in 1986, MAPS is a 501(c)(3) non-profit research and educational organization that develops medical, legal, and cultural contexts for people to benefit from the careful uses of psychedelics and marijuana. MAPS is sponsoring the most advanced psychedelic therapy research in the world: Phase 3 clinical trials of MDMA-assisted therapy for PTSD. Since MAPS was founded, philanthropic donors and grantors have given more than \$130 million for psychedelic and marijuana research and education. MAPS has earned both the [Guidestar Platinum Seal of Transparency](https://www.guidestar.org/profile/59-2751953) < <https://www.guidestar.org/profile/59-2751953> > and a [4-Star Rating from Charity Navigator](https://www.charitynavigator.org/ein/592751953) < <https://www.charitynavigator.org/ein/592751953> > .

ABOUT [MAPS PUBLIC BENEFIT CORPORATION](http://mapspublicbenefit.com) < <http://mapspublicbenefit.com> > (MAPS PBC)

MAPS Public Benefit Corporation (MAPS PBC) catalyzes healing and well-being through psychedelic drug development, therapist training programs, and sales of prescription psychedelics while prioritizing public benefit above profit. Founded in 2014, MAPS PBC is a wholly-owned subsidiary of the Multidisciplinary Association for Psychedelic Studies (MAPS), a 501(c)(3) non-profit organization. It is the parent company of MAPS EU, formed to organize and administer clinical trials of MDMA-assisted therapy for PTSD in the United Kingdom and European Union.

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[2021.12.15-Innovation-Passport-approval-letter-Midomafetamine_Redacted < https://maps.org/wp-content/uploads/2022/01/2021.12.15-Innovation-Passport-approval-letter-Midomafetamine_Redacted.pdf >](https://maps.org/wp-content/uploads/2022/01/2021.12.15-Innovation-Passport-approval-letter-Midomafetamine_Redacted.pdf)

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