

#### **EXECUTIVE INSIGHTS**

# Mind-Altering Metamorphosis: Transforming the Patient Journey in Mental Health

## **Key Takeaways**

- **1.** By 2040, psychedelic therapies, alone or combined with psychotherapy, could have transformed mental health treatment for a range of illnesses including depression, anxiety, PTSD and addiction.
- 2. Regulated digital medicine will evolve to support HCPs in the early identification of at-risk patients and enable at-home screening of potential patients eligible for psychedelic therapy.
- **3.** Psychedelic therapies will be approved across more countries, potentially reaching over 50 million patients suffering from depression, anxiety, PTSD and addiction.
- **4.** Integration of psychedelics with digital medicine will likely be necessary to deliver personalised psychedelic therapies and navigate complexities throughout the patient journey.

#### **Overview**

There is mounting interest in the use of psychedelics as standalone therapies or combined with psychotherapy, holding the potential to transform the way we treat mental health conditions. According to the World Health Organization, 1 in every 8 people globally were living with a mental disorder in 2019, with depressive and anxiety disorders being the most prevalent. Studies have reported that up to 30% of adults with major depressive disorders are resistant to pharmacotherapy, which is defined as having no response to at least two different antidepressant treatments.



Additionally, some patients exhibit severe side effects, leading to a continued high unmet need for more effective treatments. As psychedelic assets continue to progress through the clinical development pathway, and as regulation, public acceptance and supporting infrastructure become increasingly favourable, the next 10 to 20 years are likely to see a transformation in the patient journey for many mental health conditions.

In this *Executive Insights*, L.E.K. Consulting examines the exciting possibilities for a revolutionised patient journey in mental health, overcoming many of the existing challenges in today's care pathway.

## Current challenges in the patient journey

A range of challenges across the patient journey currently plague patients who have mental health conditions. Societal stigma and misconceptions may hinder individuals from seeking treatment in the first place. Limited options for effective pharmacological treatments can impede recovery. Additionally, the availability and affordability of talking therapies can be limited; clinics and therapists face capacity constraints, resulting in extended waiting times for patients. Inadequate patient monitoring to ensure adherence to treatment plans is a further challenge impeding patient care today.

In the Global Burden Disease Study 2019, mental disorders were attributed to over 125 million disability-adjusted life years (5% of the global burden).<sup>3</sup> Poor mental health cost the world economy over \$2.5 trillion in terms of poor health and reduced productivity in 2010, with a projected rise to \$6 trillion by 2030.<sup>4</sup> Furthermore, comorbidities, such as arrhythmia, chronic kidney disease, anaemia, chronic heart failure, diabetes, hypertension and rheumatoid arthritis, were more commonly observed in depression patients than in the general population.<sup>2</sup> Given the significant burden of mental disorders, it is imperative for society to take proactive steps in order to improve the patient journey and outcomes for individuals in the future.

# Charting the path: The patient journey in 2040 and beyond, across five stages

With a significant portion of individuals not responding to pharmacotherapy or psychotherapies for a range of mental illnesses, there is a pressing need for alternative approaches to mental health treatment.

Psychedelic therapy has emerged as a promising avenue to treat illnesses — including depression, anxiety, post-traumatic stress disorder (PTSD) and addiction — providing the impetus for change

with their recent proven benefits in clinical trials. As psychedelic therapies gain wider recognition as potential game changers in mental healthcare by 2040, it becomes essential to create a positive patient journey involving the safe use of psychedelics in a supportive environment. In this *Executive Insights*, we focus on the patient journey for depression (see Figure 1).

Figure 1 Patient journey in depression in 2040 New advances in **Patient** patient care in perspectives AWARENESS depression by 2040 Societal awareness and Evidence-based public education reduces destigmatisation of psychedelic stigma in mental health disorders and therapies with or without improves public perception of psychedelic psychotherapy in depression therapy with or without psychotherapy PREVENTION/ SCREENING Apps with interactive AI questionnaires for Wearable apps flag warning signs initial at-home screening enable early before symptoms worsen detection of mental health disorders At-home triaging and screening of DIAGNOSIS patients via digital apps HCPs' decisions are guided by Seamless patient experience with Al diagnostic tools efficient consultation and accurate diagnosis processes **TREATMENT** Psychedelic therapy with or without Immersive VR packages create psychotherapy, alongside digital tools psychedelic-like states to enhance the therapeutic experience Patients resistant to first-line therapy Apps for patients to track progress will be reassessed for second-line MONITORING Teleconsultation and digital data logging of Improved at-home engagement with HCPs in symptoms to track risks of relapse follow up consultations on metaverse platforms Joins virtual patient support networks

Note: Al=Artificial Intelligence; HCPs=Healthcare Professionals; VR=Virtual Reality Source: L.E.K. research and analysis

#### Stage one: Awareness

Over the next 10 to 20 years, we will witness ever-increasing societal awareness of mental health conditions as a group of disorders treatable with psychedelic therapies. This awareness is critical to close the growing mental health treatment gap, defined as the difference in the proportion of people who have a disorder and those individuals who receive care, which exceeds 50% globally, approaching almost 90% in the least resourced countries. Ongoing clinical research and societal education will drive this awareness by generating more data on the effectiveness and safety of psychedelics, particularly for patients who do not respond to current treatments. Our analysis suggests that upwards of six psychedelic assets are likely to come through the pipeline in the next 10 years, offering more therapeutic options for those in need.

The digital medicine revolution will play a pivotal role in improving awareness of mental health conditions and psychedelic therapies by disseminating evidence-based information through digital platforms, campaigns and media. Mood tracking apps, wearables and platforms in the metaverse will further raise mental health awareness. Increased awareness in at-risk populations will lower the barrier for patients to seek counsel from healthcare professionals (HCPs).

Both mental health disorders and psychedelics will gradually lose any residual stigma that exists today, though the newest evidence thankfully suggests that there has already been a significant reduction in stigma around mental illness through the COVID-19 pandemic.<sup>6</sup>

# Stage two: Prevention/screening

By 2040, R&D efforts will have advanced sufficiently to lead to a better understanding of the underlying causes of mental health conditions, allowing for better segmentation of patients and more active personalised or targeted 'wellness' (rather than treatment) plans.

Clinically approved artificial intelligence (AI)-driven screening tools have surged ahead, making their way into both homes and clinical environments. Regulated digital medicine in the form of wearables with evidence-based platforms may identify early warning signs of mental health conditions based on behavioural patterns and suggest prevention strategies to minimise the risks of worsening symptoms. If symptoms do worsen, these apps feature interactive questionnaires for at-home screening, enabling patients to assess risk of mental health disorders and receive guidance on next steps before symptoms exacerbate.

Use of digital medicine technologies streamlines the initial triaging process by supporting HCPs in assessing potential patients eligible for psychedelic therapy. As AI becomes a trusted ally for HCPs, we can expect the tools to be fine-tuned to minimise false positives. Patients identified as suitable candidates will receive automated referrals to HCPs for a comprehensive evaluation.

## Stage three: Diagnosis

Through 2040, digital medicine technologies will continue to revolutionise formal diagnosis in healthcare practices. They will support HCP diagnosis by managing patient volume and interpreting clinical data, addressing today's capacity constraints of face-to-face consultations.

Diagnostic tools leveraging digital biomarkers become mainstream, providing valuable insights into patients' conditions. Digital platforms consolidate pre-filled patient screening and clinical data, shortlisting treatment options and offering personalised treatment recommendations that consider efficacy and risk statistics. These digital tools reduce HCP decision-making time and streamline the assessment process for a seamless patient experience.

Enhanced understanding of disease mechanisms will refine patient population segmentation, leading to significant advancements in developing a more detailed or unified Diagnostic and Statistical Manual of Mental Disorders.

# Stage four: Treatment

On a 20-year time horizon, traditional selective serotonin reuptake inhibitors (SSRIs) and other established therapies (e.g. SNRIs, TCAs) will likely no longer be the first line of therapy for most patients with depression. When SSRIs are displaced by other better treatments earlier in the disease course, patients will benefit from early disease modification that will ultimately lead to better outcomes and cost savings. Instigating rapid remission for first episode or first presentation will be the primary treatment aim.

Psychedelic therapy emerges as a promising option to achieve this goal — brought forward in the treatment paradigm driven by the limited options for durable effective treatments of SSRI-resistant depression and corresponding significant side effects. Advances have been made in determining which of the many available psychedelic therapies is best suited for each patient under specific circumstances. Additionally, we will better understand drug dosing

requirements at an individual level, as well as have better clarity around what kind of, and how much, pre-dose preparation and post-dose support psychotherapies are required (if at all).

With advancements in psychedelic research, a wider range of psychedelic compounds may become accessible. Some of these may be second-generation with modifications to improve efficacy or minimise hallucinogenic effects. This may expand the eligible patient population to patients who previously did not want to undertake psychedelic therapy and could even facilitate at-home treatment protocols.

As psychedelic therapy requires careful monitoring by HCPs, first-round therapy takes place in clinics; subsequent rounds could occur via teleconsultation or group therapies to minimise capacity constraints. Psychedelic therapy is complemented by digital tools, including immersive virtual reality (VR) packages, which simulate psychedelic-like states through sounds and visuals to help prepare the patient for therapy; patient companion apps to track treatment progress; and clinical tools that predict patient outcomes and deliver personalised treatment programmes (see Table 1). Digital therapeutics delivering post-dose psychotherapeutic programmes could be either validated clinical-grade or wellness-oriented products. These digital programmes aim to extend remission or increase the duration of the treatment's effects by assisting patients in integrating their psychedelic experiences and capitalising on the neuroplastic state.

"Tackling the challenges currently faced in the treatment of mental health will require the introduction of highly effective novel therapies supported by therapeutic frameworks for personalisation. At GH Research, we are striving to maximise the clinical benefit for each patient by developing novel ultra-rapid and durable mental health treatments with individualised dosing, aiming to deliver exactly what they need on their personal path to recovery."

Theis Terwey, PD Dr med, CEO and co-founder GH Research

**Table 1**Examples of digital tools that can support HCPs in the delivery of psychedelic therapies

Type of product	Examples	Use case
Patient preparation for psychedelic therapy	SoundSelf	VR package that uses sounds and visuals to give patients access to psychedelic-like states prior to psychedelic therapy
Clinical tools to accompany psychotherapy	MindMed	MindMed's Session Monitoring System is currently in development towards FDA CDRH regulatory labelling for esketamine and LSD
	Beckley Psytech	Clinical tools are in development to track, report and predict patient outcome in order to deliver personalised treatment programmes
	Enosis Therapeutics	VR-enabled psychedelic psychotherapy that helps therapists guide patients through therapy
	Wavepaths	App adapting music to the needs of the patient and the therapist to support people during the trip
	Kernel	Wearable that can collect real-time brain activity before, during and after a psychedelic experience
Patient companion tool	TripApp	App-based tool with guided meditation and breathwork and information on psychedelics
	COMPASS Pathways	App supporting patient care via reminders and tracking of treatment process
	ATAI Life Sciences	Digital therapeutics platform providing personalised and scalable treatment via digital biomarkers to predict patient's recovery pathways and inform treatment decisions

In future, mainstream psychiatry and psychology as well as prominent psychedelics-related advocacy groups, such as the Psychedelic Patient Advocacy Network (PsyPAN),<sup>8</sup> will continue to advocate for patient rights in mental health, strive for improved access to care, and promote the integration of evidence-based practices, thereby fostering a supportive and inclusive environment.

# Stage five: Monitoring/follow up

By 2040, digital tools will promptly identify patients who have not adhered to proper tracking of treatment progress. Both passive digital biomarker-based and self-reported data inputs provide support with relapse detection, with the passive method potentially enabling earlier detection of a decline in mental health state.

Digital data logs are integrated seamlessly with electronic health record systems and processes, allowing patients to record symptoms and triggering alarms in case of relapse or recurrence. Patients who display signs of relapse are screened and triaged to determine their suitability for second-line or alternative psychedelic therapies.

Formation of virtual networks within the patient community, integrating with support provided by patient advocacy groups, further helps identification of early signs of relapse or worsening mental health. At-home follow-up teleconsultations or a metaverse engaging patients in outpatient settings throughout the patient journey will enable a seamless experience.

"MindMed's vision for the future of psychiatry and brain health is that the newest and most effective interventions are available to patients who need them and are fully covered by third-party payers, globally. Our aim is to ensure the quickest relief from suffering, and by doing this we hope to continue to prove that early and effective treatment can significantly affect the course of people's lives. We are optimistic about the role that psychedelics can play in achieving this outcome."

Daniel R. Karlin MD MA

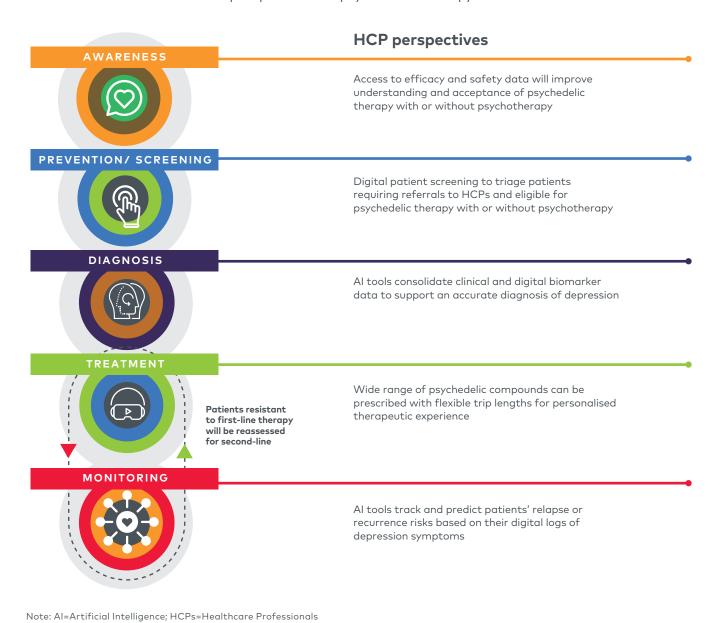
#### Biotech and digital medicine: Driving the change

In July 2023, regulatory approval for psychedelics, specifically MDMA for PTSD and psilocybin for depression, was granted in Australia for medicinal use at a national level. Switzerland, Canada and Israel have also permitted clinicians to use certain psychedelics under specific circumstances for patients with severe conditions. In January this year, Oregon became the first state in the United States to legalise the adult use of psilocybin, which has shown promise in treating severe depression, anxiety and PTSD. It is expected that similar assisted therapeutic regimens could be approved in more countries as early as 2024.9

Conservative estimates predict that globally, over 50 million patients across those three conditions could be eligible for this type of therapy, potentially transforming the mental health landscape.<sup>10</sup>

Biotech companies must prioritise strategies to shape and transform the patient journey. Integration of digital medicine players is imperative to effectively deliver personalised care and navigate the complexities throughout the patient journey. Securing regulatory approval for psychedelic therapies across more countries and ensuring adequate reimbursement plans for cost-effective treatment are other vital objectives to ensure health equity for all patients who can benefit from the therapies (see Figure 2).

Figure 2
HCP perspectives on psychedelic therapy in 2040



Source: L.E.K. research and analysis

## How L.E.K. Consulting can help

As mental health assumes an increasingly prominent role in the healthcare system, we help organisations address a range of key issues, creating value for our provider clients and across the investment landscape. We assist clients with their commercial and growth strategy, supporting them in growing sectors such as psychedelic drugs. Our approach helps organisations consistently make better decisions, deliver improved business performance and create greater shareholder returns.

To find out more and for a further discussion, please contact Adrienne Rivlin, Partner, at a.rivlin@lek.com.

#### **Endnotes**

- <sup>1</sup> https://www.who.int/news-room/fact-sheets/detail/mental-disorders
- $^2 \, https://bmcpsychiatry.biomedcentral.com/articles/10.1186/s12888-019-2222-4\#:-:text=Treatment\%2Dresistant\%2Odepression\%2O (TRD), MDD\%2Opatient\%2Opopulation\%2O\%5B1\%5D$
- <sup>3</sup> https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370(22)00405-9/fulltext
- 4 https://www.thelancet.com/journals/langlo/article/PIIS2214-109X(20)30432-0/fulltext
- <sup>5</sup> https://pubmed.ncbi.nlm.nih.gov/32047393/
- 6 https://www.bmj.com/content/369/bmj.m1379/rr#
- <sup>7</sup> https://www.cambridge.org/core/journals/cns-spectrums/article/digital-health-technologies-and-major-depressive-disorder/6CFAF96395D14 355F302B23EEE0334E2
- 8 https://www.psypanglobal.org/goals.html
- 9 https://time.com/6253702/psychedelics-psilocybin-mdma-legalization/
- <sup>10</sup> https://www.laingbuissonnews.com/healthcare-markets-international-content/features-healthcare-markets-international-content/insight-building-the-necessary-infrastructure-for-psychedelics/

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Dr Adrienne Rivlin is a partner in L.E.K.'s Healthcare practice, based in the London office. She advises private- and public-sector organisations across the pharmaceutical, biotech, medical device and consumer healthcare sectors on their critical commercial challenges, including corporate and portfolio strategy development, product launch, pricing and market access, clinical governance structures and processes, and commercial and regulatory due diligence.

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