dsm-firmenich

Unlocking the potential of CBD in modern medicine

A guide to the latest clinical evidence shaping patient-centric solutions

Whitepaper • May 2025

What's inside?

Harness the scientific promise of CBD today for the medicines of tomorrow

What if there was a therapeutic compound that could transform healthcare as we know it?

We believe cannabidiol (CBD) holds that potential.

Emerging clinical evidence reveals the significant promise of CBD in numerous health indications—driving increased research investment and creating rich opportunities to unravel the many potential therapeutic applications of this molecule.

This whitepaper has been designed to help innovators in pharma join the frontier of CBD-based research and development. It spotlights three key therapeutic areas where CBD science (and interest) is strongest—pain, anxiety, and central nervous system (CNS) disorders (Figure 1)—while illuminating newer, yet highly promising avenues for CBD research, such as women's health. In addition, the whitepaper highlights key formulation and regulatory considerations to maximize success in this rapidly evolving space.

Top therapeutic areas in ongoing CBD research

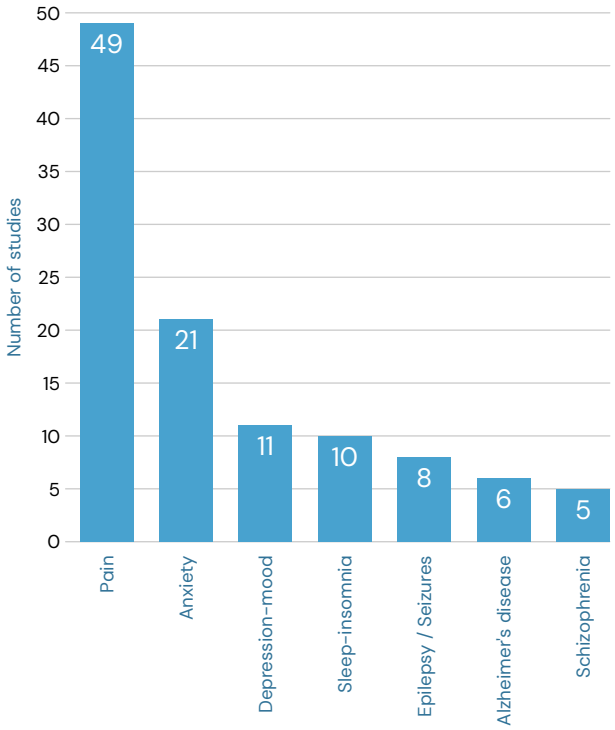

Figure 1. Ongoing clinical studies in the top therapeutic areas in CBD clinical research.[1]

"We are at a tipping point in CBD research, where expanding scientific insights are unlocking significant opportunities to transform treatment possibilities for patients worldwide."

Zdravka Misic
Associate Innovation Director Pharma, dsm-firmenich

The real-world impact of CBD

Pioneering research in the cannabinoid space has already led to the launch of several therapies—including Epidiolex®, the first-ever CBD-based drug. It was approved in 2018 for the management of treatment-resistant pediatric epileptic syndromes.[2] Epidiolex® demonstrates how CBD-based treatments can significantly enhance patient outcomes, setting the stage for further innovation.

1 Chronic pain management

Individuals aged 26–57 purchasing commercialized CBD-based products do so for **pain relief**.[3]

Chronic pain is a common yet complex problem, affecting over 30% of people worldwide and arising from a diverse range of causes, that are not always well understood.[4]

Despite its prevalence, treatment options are limited. Moreover, many analgesic drugs currently prescribed for chronic pain management are primarily designed to treat acute, short-term pain—rather than the persistent discomfort associated with chronic pain.

Promising emerging evidence suggests that CBD could pave the way for more suitable chronic pain treatment options—sparking significant scientific investment in this field to build the clinical evidence. A recent review and meta-analysis of 15 studies concluded that CBD—alone or in combination with tetrahydrocannabinol (THC)—could effectively reduce pain, with reported reductions ranging from 42% to 66%.[5] Furthermore, CBD has been reported to support with chronic pain management in multiple pain-related conditions, including arthritis of the hand[6,7] and knee,[8] chronic back pain,[5] peripheral neuropathy (damage to the nerves in the body's extremities, such as legs and feet),[9] and persistent pain that had previously been managed with opioids.[10] However, due to the complex and diverse nature of chronic pain, the overall clinical data have been variable so far, highlighting the need to further explore and validate encouraging findings.

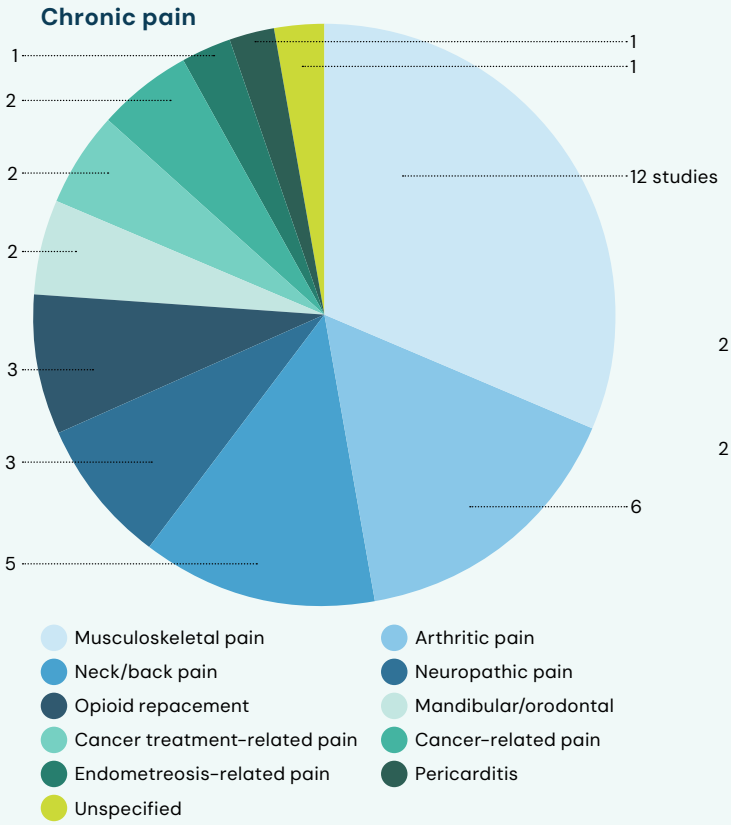

Figure 2a. Types of **chronic pain** investigated in ongoing clinical studies with CBD (total=38 studies).[1]

40+ **ongoing clinical trials** are investigating CBD as an intervention for **pain**[1]

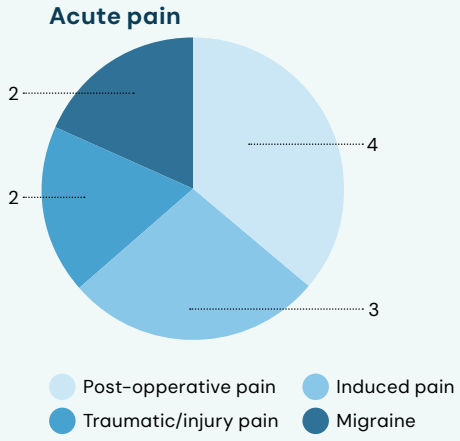

Figure 2b. Types of **acute pain** investigated in ongoing clinical studies with CBD (total=11 studies).[1]

2 Mental health

With increased societal awareness of the importance of mental health, managing anxiety, stress, mood disorders, and burnout has become a priority for many—and there is a growing body of evidence to suggest that CBD could play a key role here.

Anxiety

Numerous clinical studies demonstrate the potential of CBD as an anxiolytic treatment, alone and in combination with other components, such as THC.[11] A recent meta-analysis of eight studies found that CBD had a substantial and significant impact on anxiety,[12] including one study which reported that the stress scores in patients who received a single dose of CBD were reduced by up to 78%, compared to placebo.[13]

Positive effects of both short and long term CBD administration has been seen across various anxiety disorders including social anxiety, generalized anxiety, and post-traumatic stress disorders.[12] What's more, in one study, the anxiolytic effects of CBD were reported to last for up to one month after participants had stopped taking the medication.[14] CBD-based therapy has also shown promise in reducing symptoms of emotional exhaustion and burnout—conditions which can result from long term, chronic stress and anxiety.[15]

Mood disorders

Other mood disorders are also of great interest in CBD research, with a number of studies ongoing to examine the impact of the ingredient in conditions including depression and bipolar disorder.[1] The pre-clinical evidence in this area is promising,[16,17] and a number of clinical trials with medicinal cannabis or with CBD-based treatments have reported improved antidepressive effects as a secondary endpoint.[14,15,18] However direct clinical evidence in these conditions is so far limited, highlighting the need for randomized controlled clinical trials to realize the potential of CBD in mood disorders.

People aged 26-41 that consume over-the-counter CBD-based products report that they do so to **alleviate anxiety**[3]

3 Central nervous system (CNS) disorders

In 2018, Epidiolex® became the first CBD-based medicine to be approved for treatment in patients.

The oil-based oral CBD solution is used (alone or alongside traditional antiepileptic medications) to reduce seizures in two severe childhood epileptic conditions, Lennox-Gastaut and Dravet syndromes.

CBD has been shown to be a safe and effective treatment in these conditions,[2] and clinical trials indicate that its anticonvulsant properties could also be beneficial in other forms of drug resistant epilepsy[19]—which provides hope that CBD-based therapies may soon be available to more epilepsy patients.

Age-related CNS disorders

With the proven benefits of CBD in epileptic conditions, there is significant interest in how it may impact other difficult-to-treat CNS disorders—including neurodegenerative diseases like Parkinson's disease (PD) and Alzheimer's disease (AD).

These age-related conditions are becoming a growing concern worldwide as the global population ages. However, it might be possible to harness the effects of CBD to manage these conditions more effectively in the future.

Existing therapeutic options for PD and AD typically only offer symptomatic relief and do not address root causes, such as protein aggregation, oxidative stress, and neuroinflammation. However, CBD has gained attention as a promising drug candidate for more direct management of these neurodegenerative disorders.[21] In fact, a recent review of pre-clinical research highlighted multiple mechanisms of action through which CBD could exert neuroprotective effects in both conditions—including both general anti-inflammatory and antioxidant effects, and more disease-specific pathways like inhibiting protein aggregation.[22]

Moreover, emerging clinical evidence is revealing how CBD could improve the quality of life for people living with these conditions. For example, a recent open-label, prospective study reported that patients treated with CBD-rich oil saw improvements in the severity of AD-related neuropsychiatric symptoms such as anxiety, agitation, and aggression.[23] Additionally, early-stage clinical studies report that CBD could be effective in managing some of the symptoms in PD, including tremors, anxiety,[24] and sleep disturbances.[25]

The evidence in this area, including the findings highlighted here, is promising. However, more robust clinical research is needed to validate the benefits of CBD-based treatments in these neurodegenerative conditions, before bringing them to patients.

10

There are over **10 million new cases of dementia each year worldwide**—roughly equivalent to one new case every 3.2 seconds.

55

There were over **55 million people** worldwide living with **dementia** in 2020.

139

The number of people with dementia is predicted to nearly **double every 20 years**, reaching 78 million in 2030 and **139 million in 2050**.[20]

CBD in women's health: An opportunity to pioneer

Historically, women's health has been under researched and underserved. But this is changing, with increasing investment in studying therapeutic areas that affect women's lives—and CBD is gaining recognition as a promising molecule for advancing women's healthcare.

The science here is still particularly new, however initial investigations show that this area holds great potential for research and innovation. There has been particular interest in three key areas—endometriosis, menopause, and menstrual pain.

As interest and investment continues to grow in this budding area, innovators have the opportunity to explore novel and pioneering solutions to better support women's health and wellbeing.

Endometriosis

- As many as 1 in 8 women report that they manage their endometriosis-related symptoms with cannabis or CBD-based products.[26,27] The majority of these women report highly effective management with these tools, allowing up to 81.4% to reduce their usage of other medications, such as analgesics, anti-neuropathic pain medication, and anxiolytics.[28,29]
- A cross-sectional survey of 113 women with pelvic and perineal pain, dyspareunia, or endometriosis found that 23% used cannabis regularly as an adjunct to prescribed medicines, with 96% of these women reporting improvements in their symptoms, including improved muscle pain (84%), reduction in irritability, depression, and anxiety (72%), and improvement in sleep (68%).[30]
- The pathogenesis of endometriosis and its associated symptoms have been linked to the endocannabinoid system.[31,32]
- Two pre-clinical studies have reported that CBD administration was associated with significant reductions in the size of endometriotic lesions in *in vivo* models.[33,34]
- There are currently ongoing clinical trials investigating CBD as an intervention for endometriosis-related pain.[1]

Menopause

- Medical professionals have reported that a growing number of perimenopausal patients are using cannabis or CBD to manage their symptoms.[35]
- Moreover, some common symptoms of menopause—like anxiety and sleep disturbances—fall within the same therapeutic areas where CBD has shown great potential.[36]
- A study in an *in vivo* menopause model found that CBD treatment was linked to improvements in key areas affected by menopause, including bone mineral density, energy metabolism, and gut microbiome composition.[37]

Menstrual pain

- Pre-clinical evidence indicates that the endocannabinoid system may be involved in natural menstrual functions, such as the contractions used to shed the uterine lining.[38]
- In a survey-based study of women using a commercially available, high-CBD suppository, 81.1% of participants reported at least moderate improvement in menstrual pain and discomfort after two months.[39]
- One small, randomized, single-blind, placebo-controlled, observational study examining the use of a CBD-infused tampon during menstruation saw a statistically significant reduction in self-reported pain scores.[40]

Advancing the field of CBD: New pathways for innovation

An expert view

Zdravka Misic
Associate Innovation Director,
Pharma, dsm-firmenich

1. Where can innovators focus their efforts to make the biggest impact with CBD-based research?

There are many therapeutic areas in which the evidence for CBD is building, as presented above. Interestingly, many of these conditions have historically been difficult to treat and manage. If CBD research continues—particularly in these fields—uncovering the molecule's full benefits could transform treatment possibilities for many patients worldwide. Look at how many people are affected by chronic pain alone.

2. What types of research are needed to bring CBD-based therapies to patients?

Across all of these therapeutic areas, there is a need for rigorous, placebo-controlled clinical trials to provide strong evidence for the effectiveness of CBD. This is the gold-standard of trials and will help to differentiate between the actual therapeutic effects of CBD and the 'placebo effect'.

3. Are there any emerging opportunities to further elevate CBD-based research?

The majority of previous and ongoing clinical trials use oil-based oral dosage forms of CBD, which come with challenges around inter- and intra-subject variability in absorption, not to mention difficulties with accurate dosing and sensory hurdles.[41] As the delivery systems for CBD improve and diversify, innovators have the opportunity to better standardize study designs, strengthen the clinical evidence for CBD, and introduce more patient-friendly drug products to the market.

Making oral solid dosage forms of CBD a reality

Across the pharma industry there is rising demand for innovative, patient-friendly dosage forms that enhance convenience and compliance—including in the CBD market.

Traditional CBD formulations have been oil-based due to the highly lipophilic nature of the molecule, as well as its poor solubility and physical and chemical instability, which have limited drug development.

These characteristics also mean that large doses are required to confer any real therapeutic effectiveness, leading to an unpleasant sensory experience for patients that can have a negative effect on compliance. Furthermore, the absorption of oil-based CBD can vary greatly between patients and can be affected by the amount or type of food a person eats, making standardizing dosage and identifying effective dose ranges difficult.[41]

To overcome these limitations, novel solutions are being explored to help CBD innovators expand into solid oral dosage forms. This includes our pioneering solution, CBtru®.

Introducing CBtru®

CBtru® is a first-to-market, CBD drug product intermediate designed to enable solid oral dosage form development in cannabinoid medicines. It allows higher API loading, improved stability, and optimized pharmacokinetic performance—making it possible to create more bioavailable and patient-friendly solid oral dosage forms, like capsules, chewables, tablets, orally disintegrating tablets (ODTs), and others.

A groundbreaking clinical trial[42] sponsored by dsm-firmenich, investigated the absorption and pharmacokinetic profile of CBtru®. It demonstrated that the drug product intermediate is bioequivalent to Epidiolex® (the only market-approved, liquid oil-based CBD formulation) in healthy adults. The trial reported that:

1. CBtru® was safe and well tolerated in healthy adults.
2. CBtru® was absorbed into the bloodstream at a similar level compared to the reference product under fed conditions.
3. CBtru® exhibited higher bioavailability compared to the reference product under fasted conditions—indicating that this solution may offer more reliable and consistent CBD absorption that is less dependent on food intake.

Beyond oral dosage forms

CBtru® is a major step towards more patient-friendly dosage forms in the CBD market. But if we truly want to expand treatment options and realize the full therapeutic potential of CBD, innovation cannot stop at oral dosage forms. Other CBD delivery systems—such as topical, inhalation, and injectable forms—are needed to address specific disease-related needs. With decades-long formulation expertise and prototypes, dsm-firmenich can support partners in advancing such dosage forms.

Navigating the evolving regulatory landscape

An expert view

Ann Fowler
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Pharma, dsm-firmenich

1. What have been the biggest changes to CBD regulations in recent years and what opportunities does this open up for CBD innovators?

The approval of Epidiolex® for the treatment of certain epileptic syndromes has demonstrated the potential of CBD as a therapeutic agent and opened the door for future CBD-based drug products to be approved.

Additionally, the creation of legal pathways, standards or guidelines specifically tailored for CBD-containing products in several countries —such as Australia, Brazil and Canada—has allowed for the generation of new, observational evidence for the health benefits of CBD. This has fueled an increase in the number of clinical trials exploring CBD-based interventions.

2. What are the key considerations when developing CBD-based therapies for patients?

The quality of the CBD API is the primary consideration. Using the highest quality ingredient is not only essential for protecting the safety of patients, but also for maintaining regulatory compliance during clinical trials and achieving subsequent market authorization.

In order to choose the highest quality CBD API, formulators should look for Good Manufacturing Practice (GMP)-certification, as well as robust data packages for regulatory submission. Considering factors such as purity, ensuring minimal THC content, and the absence of residual solvent and elemental impurities contamination is also important.

3. Do current regulations favor any specific CBD APIs?

Many key markets, including the Australia, Mexico, and Brazil, only permit the use of CBD derived from natural sources, and not synthetic. Furthermore, the European Pharmacopeia monograph, compliance with which is mandatory for medicinal products marketed in the European Union, also excludes synthetic forms. There are several reasons for this, including:

- Natural CBD is extracted from Cannabis sativa with precise stereochemistry, while synthetic CBD is chemically created and may require additional processing to remove isomers.
- The impurity profile of naturally derived CBD is generally well understood.

dsm-firmenich, your end-to-end partner for CBD innovation

CBD-based research is primed to transform therapeutic options for patients. However, navigating this new and rapidly growing landscape presents drug developers with unique challenges—from designing robust and impactful studies, to ensuring compliance with evolving regulations.

When you partner with dsm-firmenich, our deep technical, quality, and regulatory expertise can help you enter this field with confidence.

Ready to join the frontier of CBD-based therapeutics?

Please connect with your account manager. If you are new to dsm-firmenich, contact us today to begin pioneering new possibilities and elevate patient health.

Connect with an expert

www.dsm-firmenich.com

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