



Your end-to-end partner for cannabinoid research and development

We deliver more than
cannabinoid active ingredients.

Discover how dsm-firmenich
can support you along the entire
drug development journey.

dsm-firmenich 

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Unlock new therapeutic possibilities for patients worldwide

We're passionate about pioneering the next frontier in medicine – one powered by cannabinoid research and development.

Early-stage drug development plays a critical role in expanding treatment options and convenience that will ultimately support global patient health. That's why we're invested in cannabinoid innovation – an emerging and exciting field of research with promising potential across a wide range of indications.

Together with Brains Bioceutical, manufacturer of high quality pharma-grade cannabinoids, we have created a unique end-to-end innovation platform powered by expert services. It has been designed to enhance the odds of therapeutic breakthroughs and streamline development pathways in the cannabinoid space; helping to unlock treatment possibilities and convenience for patients worldwide.

Discover new horizons in the rapidly advancing cannabinoid realm. **Partner with dsm-firmenich** for access to a high quality, GMP cannabinoid active pharmaceutical ingredient (API) portfolio, customized solutions and technical, clinical and regulatory expertise.

Learn more at:
www.dsm.com/cannabinoid-actives





Get to know the endocannabinoid system

Renewed interest in cannabinoids follows the discovery of the endocannabinoid system (ECS) in the early 1990s – a complex cell signaling network present throughout the body that helps to regulate and balance critical bodily functions, including metabolism and appetite, mood and anxiety, immunity and pain perception. Cannabinoids are understood to interact with CB1 and CB2 in the ECS – two cannabinoid receptors with distinct physical properties.² Binding to these receptors allows cannabinoids to exert multiple effects throughout the body.

Understanding cannabinoids

Cannabinoids are a group of bioactive compounds found in the *Cannabis sativa* plant. The plant naturally produces around 80-100 cannabinoids – whereby cannabidiol (CBD) and tetrahydrocannabinol (THC) are the two major cannabinoids present.

While THC is known for its psychoactive properties, CBD is non-intoxicating; making it an attractive candidate for innovation in the pharmaceutical industry. Minor cannabinoids – also referred to as rare cannabinoids or CBx – are found in much lower concentrations (1% of the total plant biomass).

Cannabinoids – especially CBD – demonstrate significant therapeutic potential in areas including central nervous system (CNS) disorders (like epilepsy), chronic pain management, mental health and mood ailments, cancer and more. Early-stage pre-clinical research on minor cannabinoids is also evolving, revealing interesting cannabinoid receptor-dependent pharmacological activity, a critical first step in understanding the complex and interactive pharmacology of cannabis-derived molecules.¹

The untapped potential of cannabinoid APIs

The cannabinoid API market is bursting with innovation – and brings a myriad of opportunities to expand treatment possibilities and address unmet patient needs through cannabinoid-based drug discovery and development.



Global cannabinoid market value in 2022³



Global cannabinoid market in 2027³



CAGR 2022-2027³

Cannabinoid science is strongest in CNS disorders

Although there is mounting evidence indicating the role cannabinoids could play across a number of indications, current cannabinoid API research and commercialization is focused on CNS diseases, mainly epilepsy, and chronic pain management (or indications related to pain or spasms).

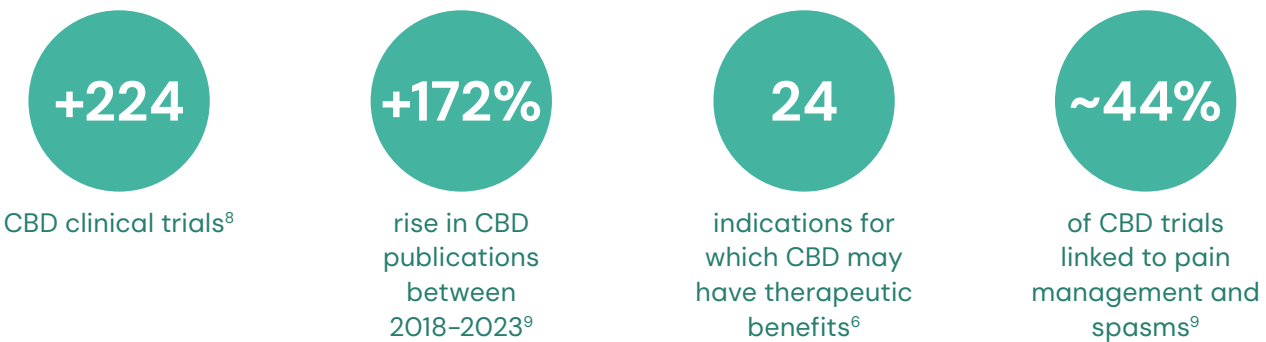
Characterized by recurrent seizures, epilepsy is the most common neurological disorder worldwide, affecting more than 50 million people globally.⁴ However, up to 70% of people diagnosed with the condition could live seizure-free if properly diagnosed and treated.⁵ Industry metrics show that the CNS market is valued to reach \$100 billion by 2025 to help address unmet patient needs.⁶ Chronic pain affects around 10% of the world's population.⁷ It can significantly impact quality of life, sleep and mood – but is difficult to treat because the condition is unique to each person experiencing it.

It is projected that CBD will bring a new wave of breakthrough innovations for the treatment of CNS diseases – especially in the fields of Alzheimer's and Parkinson's disease – and chronic pain.

Powered by positive science and a favorable regulatory landscape

As interest in cannabinoids grows, research in the field continues to expand rapidly. And this is just the beginning...

The market is still in its infancy and the therapeutic potential of cannabinoids is yet to be fully explored. With this comes an opportunity to be at the forefront of new scientific developments in the space.



Ongoing CBD clinical trials by phase and indication

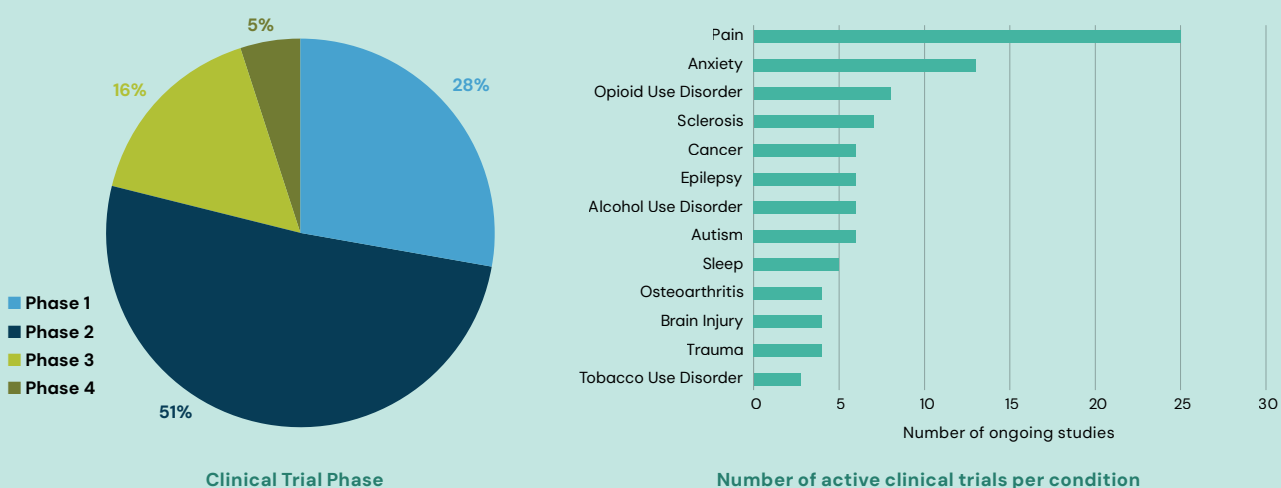


Figure 1. Ongoing CBD clinical trials by phase and indication. The majority of trials are focused on pain management, spasms and neurological disorders (including CNS diseases). However, there is strong interest in the benefits of CBD across multiple therapeutic areas as indicated above.

In parallel to growing science, regulatory developments in major geographies indicate more openness and acceptance towards cannabinoid therapies among regulators, healthcare professionals and patients. Regulatory bodies across the world, including the US Food and Drug Administration (FDA), European Medicines Agency (EMA), Therapeutic Goods Administration (TGA) in Australia,

Pharmaceuticals and Medical Devices Agency (PMDA) in Japan and National Health Surveillance Agency (ANVISA) in Brazil, are increasingly recognizing the promise of cannabinoid molecules and are taking steps to set efficient regulatory and patient access pathways for the lawful marketing of appropriate cannabinoid-based medicines.



dsm-firmenich supports you at every stage of your cannabinoid drug discovery and development journey

We offer the highest quality CBD active ingredients and end-to-end technical, clinical and regulatory expertise to help drug developers navigate the ever-changing cannabinoid market **with confidence**.

Discovery & Development

Pro-Clinical Research

Clinical Research

Regulatory Review

Post-Market Monitoring

Discovery & Development

Leveraging decades of experience, cutting-edge technologies and a pioneering mindset, we help to identify and propel novel commercially viable opportunities.

Pre-Clinical and Clinical Research

We're dedicated to developing robust cannabinoid science via our world-class scientific services – with the capabilities to facilitate novel discoveries and advancements in the developing cannabinoid market.

As well as access to the latest research, we can also support with new data generation. Our skilled clinical operations team are highly experienced in designing and executing pre-clinical and clinical studies – ready to support your clinical trial design and strategy.



400+ strong R&D team



Access to the clinical research landscape



Provision of materials, regulatory documentation and data



+25 years' experience in clinical trials



Support with study design, launch, co-ordination and execution

Regulatory Review

Our global regulatory expertise and commitment to quality give you the ultimate confidence that your cannabinoid-based drug products are compliant in fast-changing and complex markets*.

- Cannabinoid portfolio produced under ICH Q7 GMP
- Strict quality policies and advanced quality management systems
- Global network of regulatory specialists
- Feasibility assessment and gap analysis
- Cross-regional registrations and deficiency letters
- Support with pharma package adjusted to local requirements

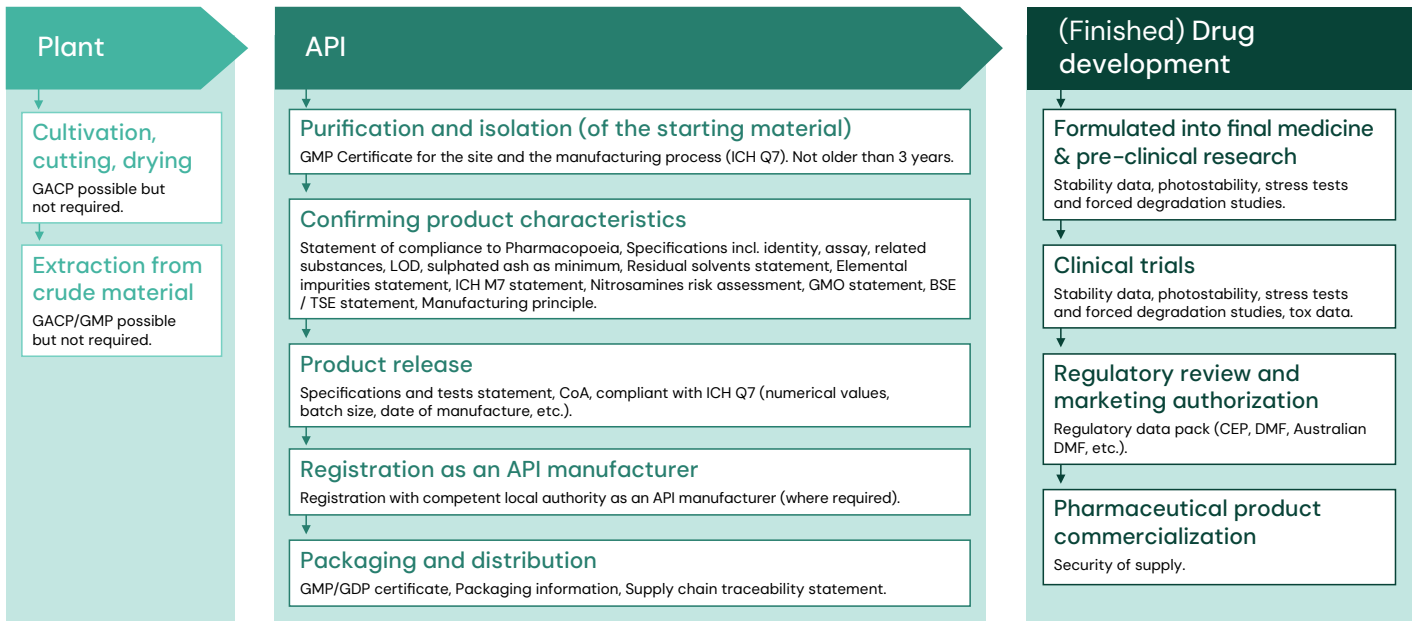
*Depending on local regulatory landscape.

Post-Market Monitoring

We have the capabilities to support with the commercial evaluation of your cannabinoid drug – integrating asset value proposition and target product profile based on latest evidence and benefit to patients beyond current standard of care. We can also remove growth challenges when commercializing by ensuring timely API supply of sufficient quantities and consistent quality. Finally, we can help to secure a viable IP strategy.



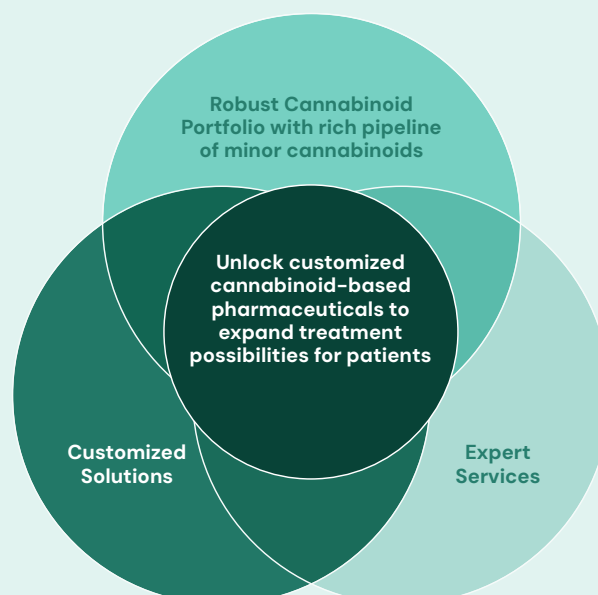
How much risk are you willing to take – every step of the way?



Enter the cannabinoid market with confidence

We go beyond CBD APIs to help our partners realize the unique potential of cannabinoid-based pharmaceuticals. As a trusted solutions provider in the cannabinoid market and wider pharmaceutical industry, we have the end-to-end capabilities drug developers need to navigate the complexities of cannabinoid-based innovation more effectively.

dsm-firmenich and Brains Bioceutical bring proven expertise to simplify cannabinoid research and development; helping to reduce risks across the entire drug development pathway and supporting your path to success. Discover how – together – we can push the boundaries of what’s possible in the cannabinoid discovery space.



Robust Cannabinoid Portfolio

We offer a robust CBD active ingredients portfolio, including a formulated CBD intermediate, that is trial-ready, the highest quality and GMP-certified. We're also developing a rich pipeline of minor cannabinoids.

All our cannabinoid active ingredients meet the highest purity, consistency and reliability standards and are delivered via a dependable supply chain that is adaptable to changing market dynamics.

Trusted CBD API

- THC-free CBD API
- 100% natural hemp derived
- Consistent quality
- Science-backed
- GMP-certified manufacturing process
- 3-year stability data
- US DMF
- EU ASMF (CEP submission in preparation)

Pipeline of cannabinoid APIs

- THC Delta 9
- THC Delta 8
- Cannabinol (CBN) crystalline solid formulation
 - Cannabichromene (CBC)
 - Cannabidiol acid (CBDA)
 - Cannabidivarin (CBDV)
 - Cannabigerol (CBG)
 - Cannabigerolic acid (CBGA)

Customized Solutions

We have the ingredient expertise and technical knowledge you need to meet patient needs *and* your drug development objectives – helping you to overcome even the most complex formulation challenges to improve the performance of cannabinoid pharmaceuticals.

Our formulation toolbox

Solutions for enhanced stability

Our unique expertise and technologies ensure that drug formulations remain stable.

Solutions for enhanced solubility

Proprietary technologies capable of enhancing active solubility and ensure dispersibility in water.

Solutions for enhanced bioavailability

Tailor-made solutions that help to optimize the adsorption and bioavailability of APIs, including cannabinoids.

Solutions for targeted delivery

Solutions for gastric protection, intestinal and colonic delivery in both monolithic and multi-particulate dosage forms.

Expert Services

Our strong commitment to innovation means that we're constantly seeking new opportunities to inspire the next groundbreaking drug development in the cannabinoid arena. We're currently exploring multiple avenues, technologies and formats to enable cannabinoid molecules – like CBD – to fulfill their potential as a therapeutic agent.

To support this, we've created a unique ecosystem of CDMOs and partners and who enhance our in-house capabilities with market-leading research platforms and formulation technologies. We also provide access to therapeutic-specific key opinion leaders with proven experience in the cannabinoid landscape.

Partner with dsm-firmenich to unlock the full therapeutic potential of cannabinoids and illuminate new possibilities for patient health globally.

Connect with one of our experts today at www.dsm.com/cannabinoid-actives



About Brains Bioceutical

Our cannabinoid innovation platform is strengthened by our partnership with Brains Bioceutical – an evidence-based and science-led pioneer of cannabinoid solutions. Brains Bioceutical produces high quality, GMP-certified cannabinoid APIs to unlock new opportunities for research and development in the pharmaceutical industry and mitigate the risk of quality-related failure in clinical assessments. With a full range of licenses and registrations, its trial-ready cannabinoid portfolio provides confidence in scientific progress and product advancements.



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