



Your end-to-end partner for cannabinoid-based innovation

We're more than APIs.
Discover how dsm-firmenich can support you along the entire drug development journey.

dsm-firmenich 



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Advancing global patient health through innovative science

Early-stage drug development plays a critical role in expanding treatment options and convenience that will ultimately support global patient health. That's why dsm-firmenich and Brains Bioceutical have created an innovation program to help unlock a new era in the pharmaceutical industry that spotlights cannabinoids – an emerging and exciting field of research with promising potential across a wide range of indications.

Discover new horizons in the rapidly advancing cannabinoid space. Partner with dsm-firmenich for access to a high quality ingredient portfolio, customized solutions and expert services; inspired by patients, and delivered by experts.

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



Introducing 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.

Discover cannabinoids

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

While THC is known for its psychoactive properties, CBD is non-psychoactive; 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 – are demonstrating significant therapeutic potential in areas including central nervous system (CNS) diseases (like epilepsy), pain disorders, mood disorders, cancer and more. Early stage pre-clinical research on minor cannabinoids is also evolving, revealing increasing 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 market is bursting with innovation – with a myriad of opportunities to expand treatment possibilities and address unmet patient needs through cannabinoid-based drug discovery and development.

\$22.1
billion

Global cannabinoid
market value in 2021³

+22%

CAGR 2022-2031³

\$154
billion

Global cannabinoid
market in 2031³

Cannabinoid science is strongest in CNS disorders and pain management

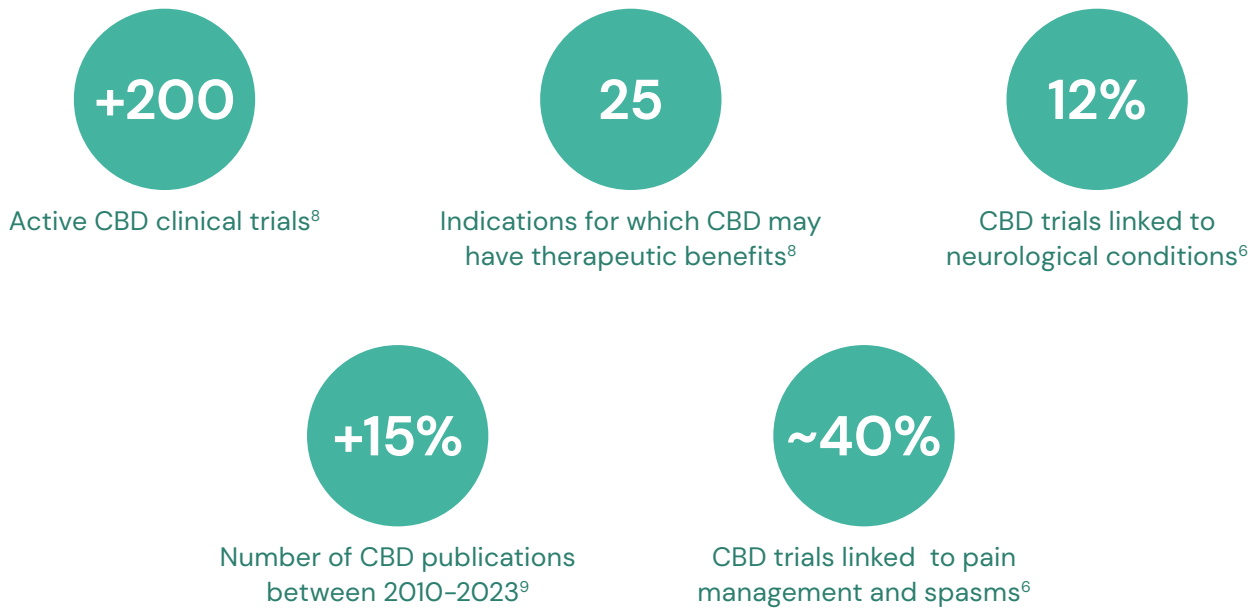
The current cannabinoid API research and commercialization is focused on CNS diseases, mainly epilepsy, and pain management (or indications related to pain or spasms), with mounting evidence on numerous additional indications.

Characterized by recurrent seizures, epilepsy is the most common neurological disorder worldwide, affecting more than 50 million people globally.⁴ Up to 70% of people diagnosed with the condition could live seizure-free if properly diagnosed and treated.⁵ Chronic pain affects around 10% of the world's population.⁶ 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 and chronic pain. The CNS market is valued to reach **\$100 billion by 2025.**⁷

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

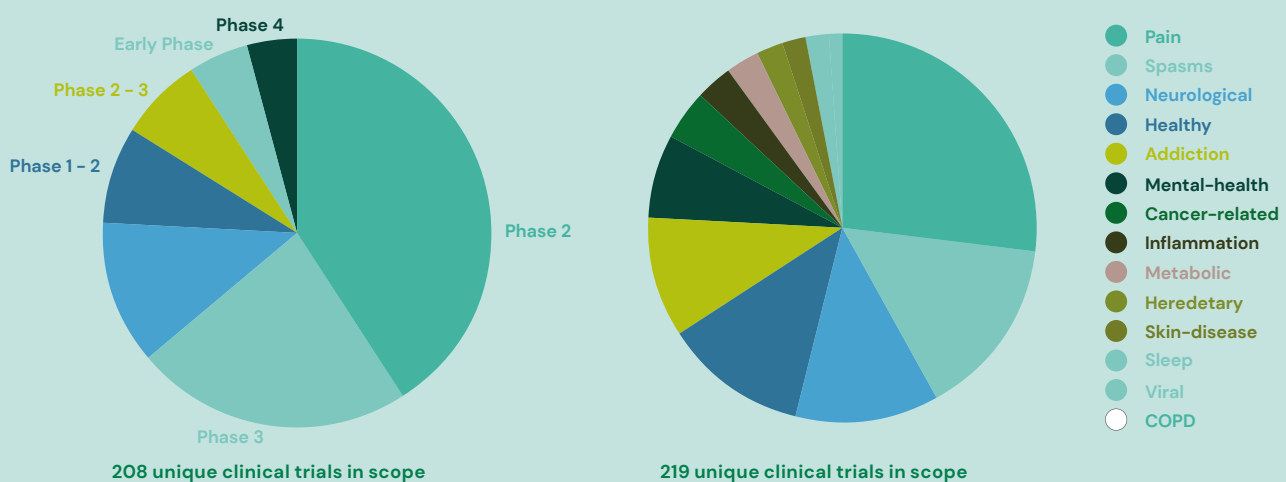


Figure 1. Ongoing CBD clinical trials by phase and indication. The majority of trials are focused on pain management, spasms and neurological disorders (including CNS diseases). However, there is strong interest in the benefits of CBD across multiple therapeutic areas as indicated.

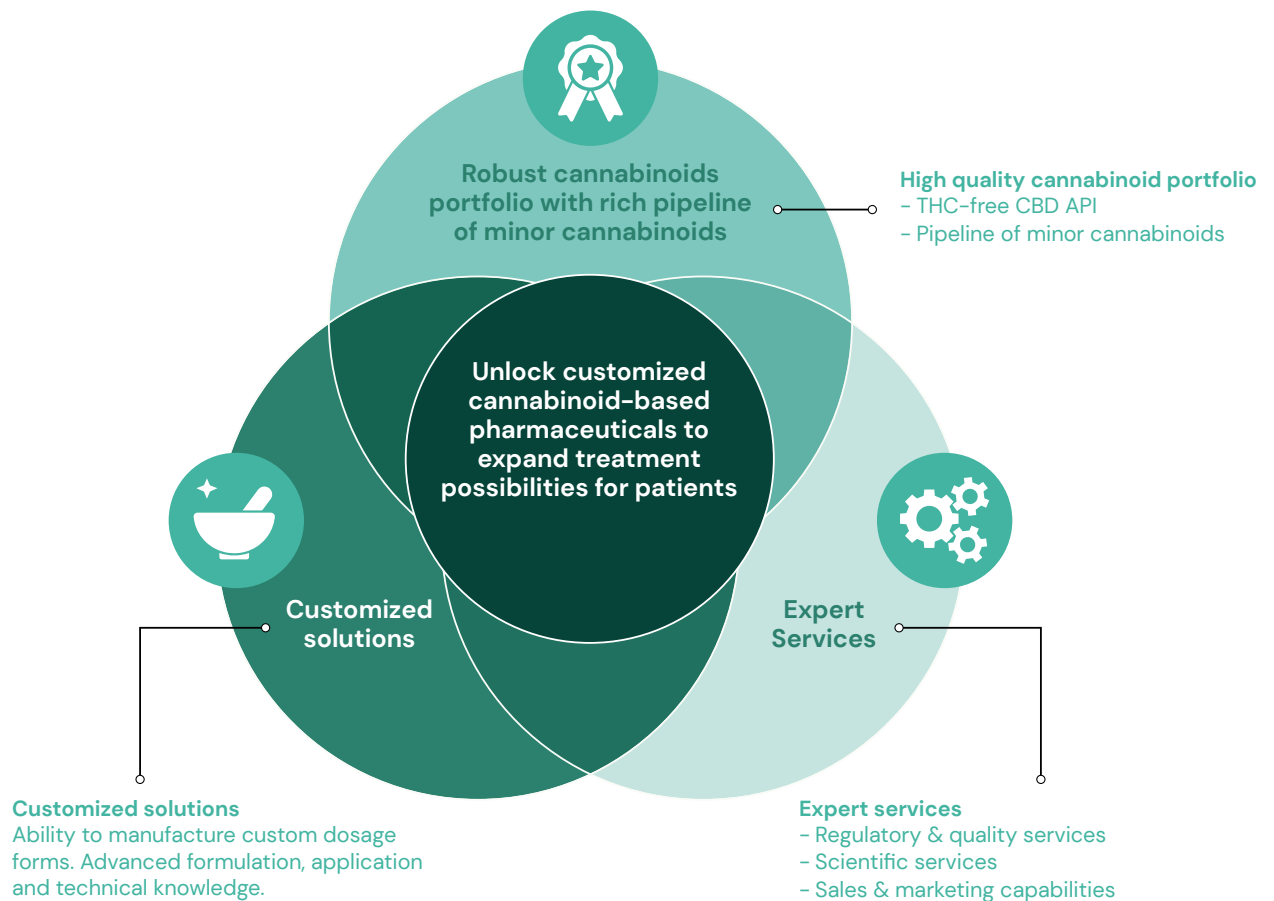
Active monitoring of regulatory developments in major geographical markets shows a changing trend towards a favorable landscape. Regulatory bodies, like the US Food and Drug Administration (FDA) and European Medicines Agency (EMA), are increasingly recognizing the promise of cannabinoid molecules and taking steps to improve the efficiency of regulatory and patient access pathways for the lawful marketing of appropriate cannabinoid-based drug products.

Think cannabinoid APIs. Think dsm-firmenich.

Enter the cannabinoid market with confidence

Entering early-stage drug development in the cannabinoid space takes more than APIs. It takes a partner that is passionate about innovation, safety and finding new ways to keep the world's growing population healthy.

dsm-firmenich and Brains Bioceutical offer a unique innovation platform inspired by patients to help unlock a new medical frontier of customized cannabinoid-based pharmaceuticals. Discover how – together – we can break boundaries in cannabinoid-based research and development, and beyond.





About Brains Bioceutical

Our cannabinoid platform is enabled by Brains Bioceutical – an evidence-based and science-led pioneer of cannabinoid solutions. Brains Bioceutical produces the highest quality cannabinoid APIs to unlock therapeutic innovation 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 advancement and product development.

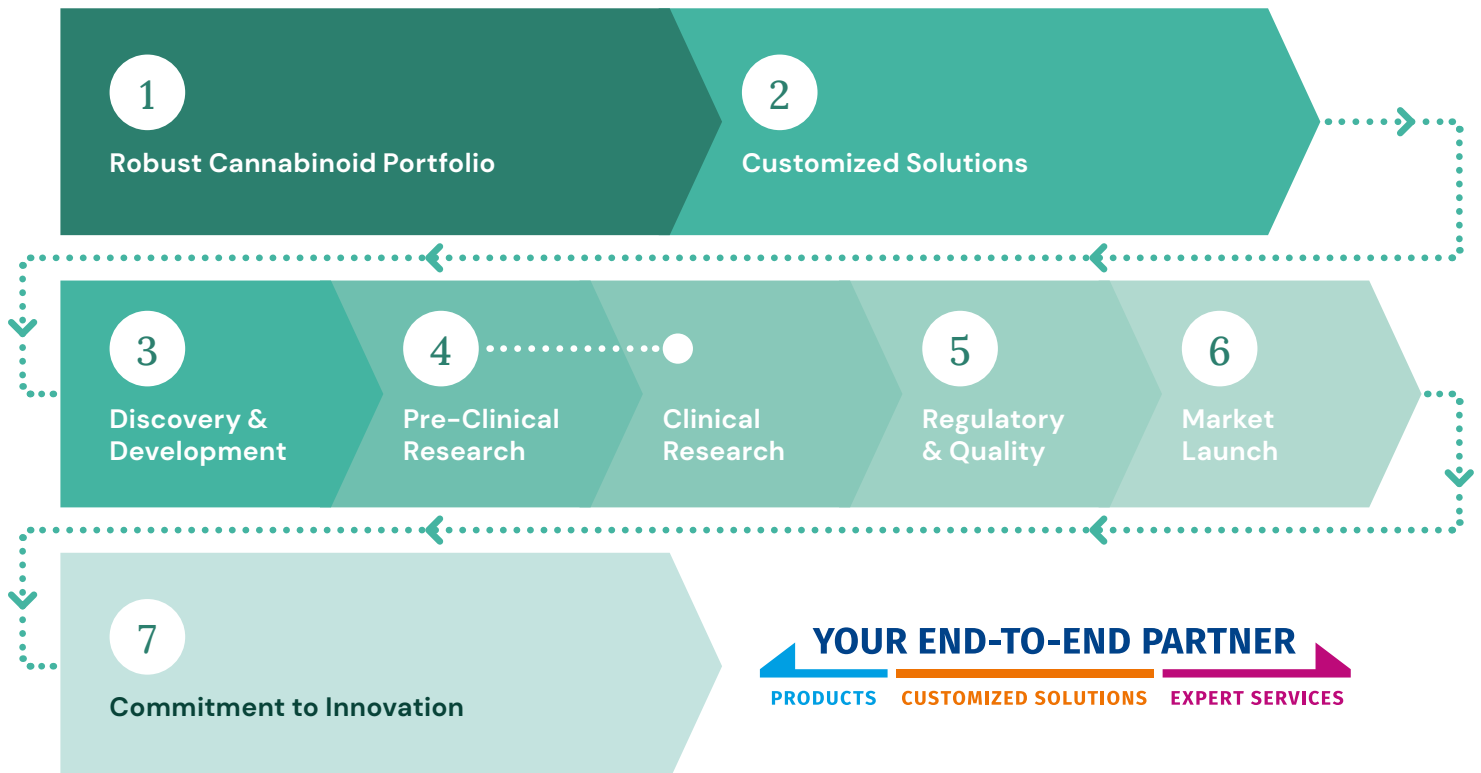


Want to deliver patient driven cannabinoid solutions?
Start the conversation at www.dsm.com/cannabinoid-actives

Your end-to-end partner

Supporting you at every stage of your cannabinoid drug development journey

Together with Brains Bioceutical, we have the cannabinoid API portfolio, leading-edge technical expertise, regulatory know-how and scientific services you need to navigate the ever-changing cannabinoid market **with confidence**.



1 Robust Cannabinoid Portfolio

We offer a robust cannabinoid API portfolio that is trial-ready, the highest quality and available in finished dosage form. We're also developing a rich pipeline of minor cannabinoids.

Trusted CBD API

- THC-free CBD API
- 100% natural hemp derived
- Consistent quality
- Science-backed
- GMP-certified
- 3-year stability data
- UK MHRA registered
- US DMF
- EU ASMF

Pipeline of cannabinoid APIs

- THC Delta 9
- THC Delta 8
- CBN crystalline solid formulation
- Other minor cannabinoid ingredients:
 - Cannabichromene (CBC)
 - Cannabidiol acid (CBDA)
 - Cannabidivarin (CBDV)
 - Cannabigerol (CBG)
 - Cannabigerolic acid (CBGA)

2 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 and application challenges to improve the performance of cannabinoid pharmaceuticals.

Did you know, we also have the capability to manufacture customized finished dosage forms flexible to your needs?

Our technical solutions toolbox

Enhanced stability

Our unique expertise and technologies ensure that drug formulations remain stable, independent of the application format or storage conditions.

Improved solubility

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

Increased bioavailability

Range of tailor-made solutions that help to optimize the adsorption and bioavailability of cannabinoids.

Targeted delivery

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

3 Discovery & Development

4 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,
documentation and data

- Drug substance section (DS) for investigational medicinal product dossier (IMPD) available.
- Drug product section (DP) available for different dosage forms via commercial partner



+25 years'
experience
in clinical trials



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

Regulatory clinical approvals:

- FDA IND opened for PK Study
- MHRA CT approval for PK Study
- TGA approval in-human Proof-of-Concept studies

5 Regulatory & Quality

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

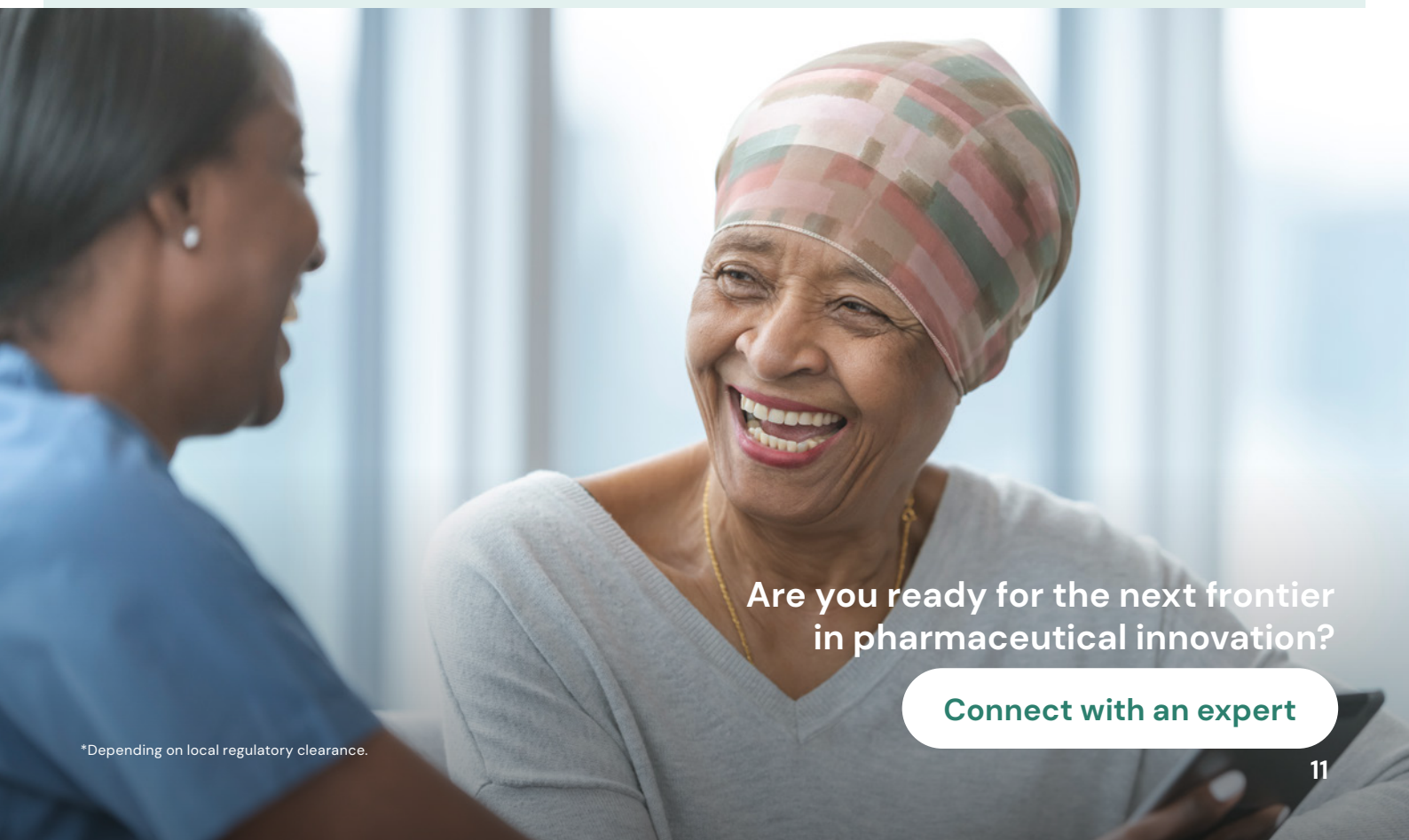
6 Market Launch

We have the capabilities to support with the commercial evaluation of your cannabinoid drug and securing a viable IP strategy.

7 Commitment to Innovation

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

To support this, we've created a unique ecosystem of CDMOs and partners who enhance our in-house capabilities with market-leading research platforms and formulation technologies.



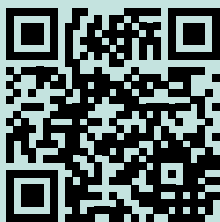
Are you ready for the next frontier
in pharmaceutical innovation?

[Connect with an expert](#)

*Depending on local regulatory clearance.

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



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