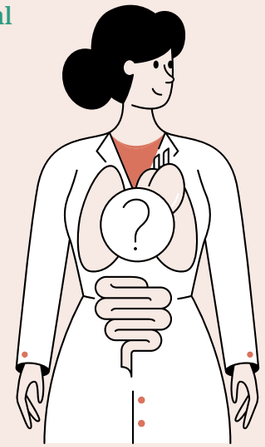
The clinical trials roadmap

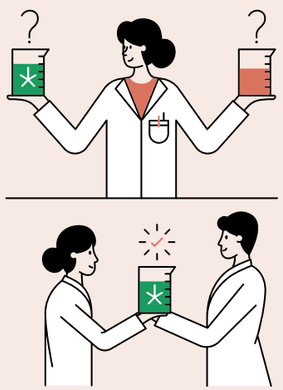
Established in 2018, with medicinal cannabis cultivation & processing facilities established in Lesotho and under construction in Portugal, EuroCan is in the vanguard of the fast-growing, legalised medicinal cannabis industry. In this article, EuroCan's Chief Technical Officer, Miguel Fagundes, a qualified pharmacist specialising in the pharmaceutical industry, gives his insight on the process of clinical trialing of new medical interventions, a topic which is of great relevance in the developing legal cannabis sector, from over-the-counter CBD products to pharmaceutical products prescribed by specialist medical professionals.



What is a clinical trial?

A clinical trial is a research study conducted in humans with the goal of answering specific questions about new therapies, vaccines, diagnostic procedures or new ways of using known treatments (together referred to as "interventions"). Carefully conducted clinical trials are the fastest and safest way to find effective treatments that help people.

Clinical trials are an integral part of the drug and diagnostics discovery and development process. Before a new intervention can be made available, evidence of its safety and efficacy must be proved by well-designed, well-controlled, and carefully monitored clinical studies in consenting participants. Randomized controlled study is the most reliable medicine study design.



What is measured in a clinical trial?

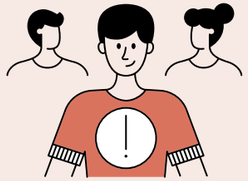
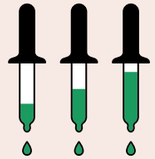
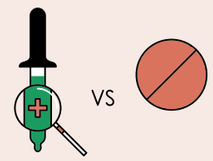
Clinical trials are performed in human volunteers to provide answers to questions such as "does a treatment work?", "does it work better than other treatments?" and "does it have side effects?"

The plan/protocol for clinical trials will describe the results ("endpoints") that will be measured and the type of information to collect; this is then shared with regulatory authorities to obtain marketing approval, which - when granted - allows a company to market its product for sale.

Clinical trials also provide important information on the cost-effectiveness of a treatment, the clinical value of a diagnostic test and how a treatment improves quality of life.

How many phases are needed in a clinical trial?

Clinical trials are conducted in phases. Each phase is designed to answer certain questions, while taking steps necessary to safeguard participants. Every treatment is usually tested in three phases of clinical trials (conducted according to Good Clinical Practice (GCP) guidelines) before regulatory agencies consider the product to be safe and effective. Clinical trials for the drug candidate commence only after pharmacokinetics and pharmacodynamics have been studied. An overview of the phases of clinical trials can be summarised as follows:

Phase 1	Phase 2	Phase 3	Post-Marketing Surveillance Trials
What happens to the compound in the body from a safety & tolerability point of view	Safest and most effective dosing regimen for the medicine	Adequately confirm the benefit and safety of the medicine	Evaluate the long-term effects of the medicine
6-10 participants	20-300 participants	300 - 3,000 participants	Anyone seeking treatment
			
Using a small number of healthy participants, the goal is to study what happens to the investigational compound in the body from a safety and tolerability point of view. Study participants are monitored for the occurrence and severity of side effects.	Once the initial safety of the study drug has been confirmed in Phase I trials. Participants are given various doses of the compound and closely monitored to compare the effects and to determine the safest and most effective dosing regimen.	These studies allow for the safety and efficacy of the new investigational drug to be compared to other available treatments or placebo. As well as being tested in combination with other therapies. Information obtained is used to determine how the compound is best prescribed to patients in the future.	Once the medicine has received regulatory approval (or market authorization) - these studies are designed to evaluate the long-term effects of the drug (broader efficacy and safety information). Under these circumstances, less common adverse events may be detected.

Relevance to cannabinoids?

Until recently, despite the therapeutic qualities of cannabis which have been well known for many centuries, it has not been easy to carry out testing or research into medicinal cannabis products due to the prevailing legal restrictions. With the liberalisation of legislative and societal attitudes towards cannabis we expect that growing scientific interest will further explore the clinical relevance of the various cannabinoids found within the cannabis plant, through clinical trials. As these controlled and scientifically designed studies and trials progress, we anticipate a range of positive results which will demonstrate product safety, efficacy and the potential to improve quality of life for patients, whilst also further educating both scientists and the general public into the potential benefits of cannabinoids.

A DIVISION OF BOTANICAL HOLDINGS PLC
www.botanicalholdings.com

info@euro-can.eu / www.euro-can.eu

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