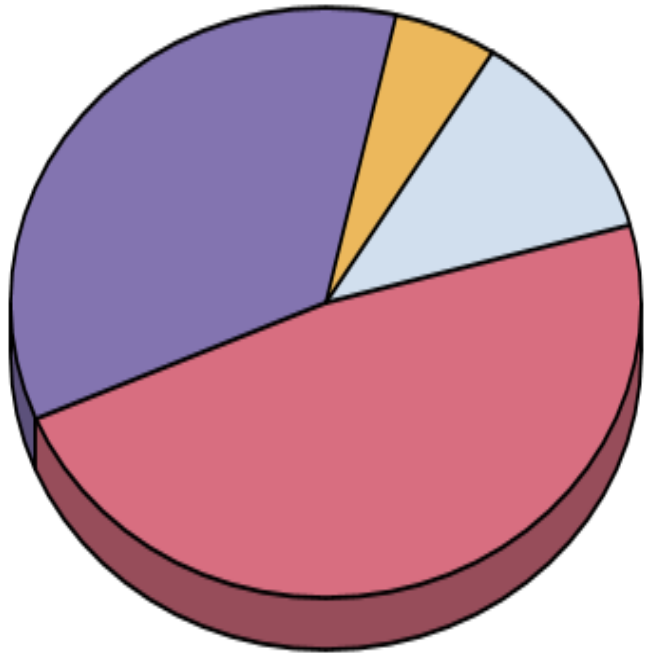


Using Israel as a Guideline

Micha Mesure
Wake Law Group



Percentage of Registered Studies by Location



**Non-U.S. only
(48%)**



U.S. only (35%)



**Both U.S. and non-
U.S. (5%)**



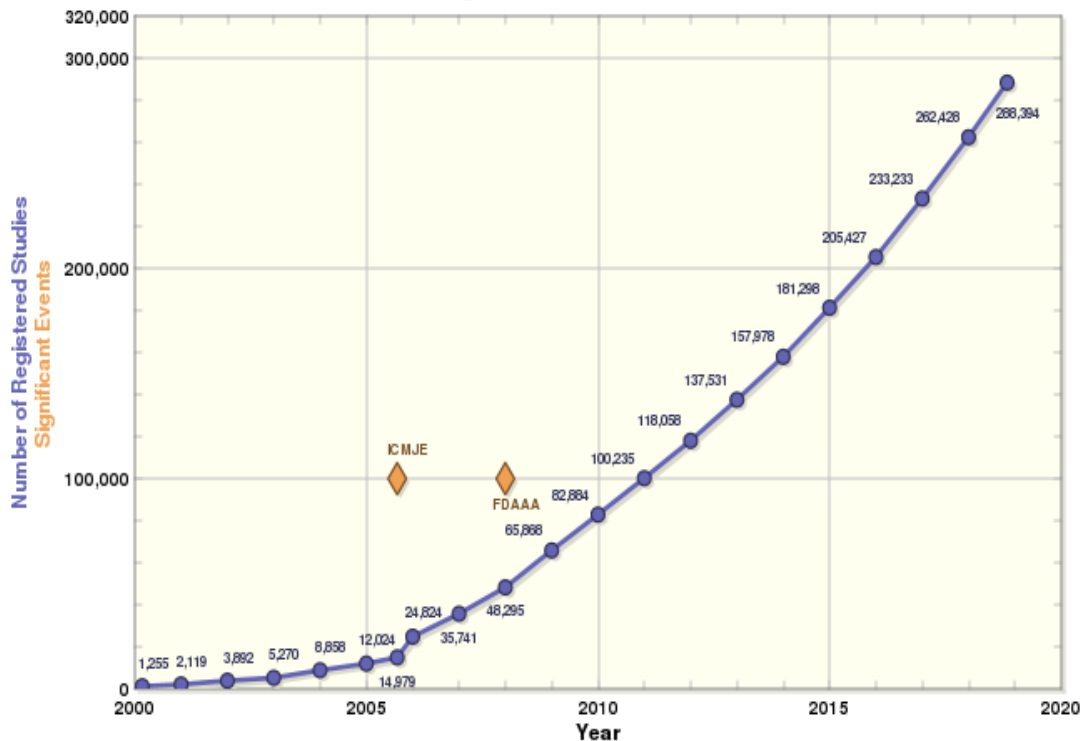
**Not provided
(12%)**

(as of November 01, 2018)

Total of 288,732 studies

The Increase

Number of Registered Studies Over Time
and Some Significant Events (as of October 31, 2018)



Source: <https://ClinicalTrials.gov>

- 80 % of applications for drugs & biologics contain data from ex-U.S. studies
- 78 % of all subjects were enrolled outside the U.S.
- 87 % of all subjects in recent biologics trials were enrolled outside the U.S.

Driving Forces of International Clinical Trials

- Reduced cost
- Faster recruitment rates
- Availability of large number of patients
- Less regulatory red tape
- Less Insurance preclusions

Barriers to Clinical Research on Cannabis in the United States

- Obtaining Cannabis
- Federal Law
- Lack of available funding
- Obtaining Approval



Israel and Cannabis

“We believe cannabis should be a medicine like any other medicine.”

– Yuval Landschaft, director of the Health Ministry’s Medical Cannabis Unit



Why Israel

- **Advanced Technology**
 - Netafim Ltd.'s drip-irrigation system
 - Seed company Hazera Ltd.'s specially bred seeds
 - Labs have modified marijuana's molecular structure to standardize cannabinoids to specific receptors that can be used for treating symptoms



Straight Forward Application



State of Israel
Ministry of Health
משרד הבריאות, ישראל

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English > [Services](#) > [Medical Services](#) > Application for a permit to hold and use cannabis

Services

Licensing of Medicine >
and Health
Professions

Medical Services

Databases

Forms by target sector

Application for a permit to hold and use cannabis

Service Description

Background

The Medical Cannabis Unit is the authorized unit in the Ministry of Health to examine applications and issue permits to hold, use and research dangerous drug under the Dangerous Drugs Ordinance.

The Medical Cannabis Unit examine medical recommendations to use cannabis for medical purposes, in accordance with the [established procedures](#).

This page details the process for the **patient** in order to obtain medical cannabis license. The recommending specialist should review the [cannabis permits procedure \(Procedure 106\)](#) and follow its instructions.

* To apply for a usage **permit for cannabis research** or for research that includes contact with cannabis, please follow the [instructions](#) on the Ministry of Health's site

The process for the patient in order to obtain medical cannabis permit includes the following steps:

1. Submission of a specialist's recommendation for permit
2. The Medical Cannabis Unit is receiving the recommendation
3. Examination of the recommendation based on the relevant criteria and indications
4. Decision to approve or reject the application
5. Issuance of a permit

Forms

- > [Application for a Medical Cannabis Permit, to be completed by a specialist](#)
- > [Instructions to the physician to complete an online application for Medical Cannabis Permit](#)
- > [Application to appeal Director's decision](#)
- > [Appendix to the Application for a supportive treatment with cannabis to PTSD patients](#)

Circulars and procedures

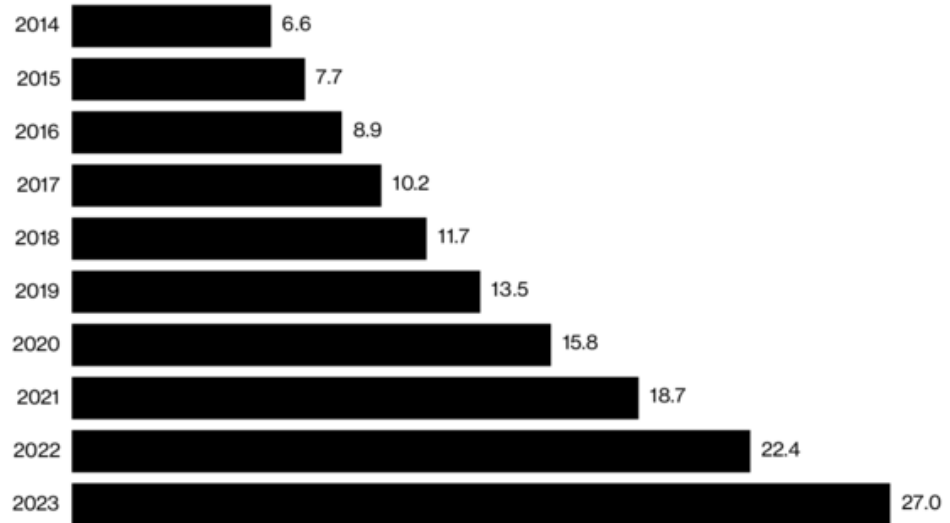
- > [Cannabis Permits Procedure \(Procedure 106\)](#)

Israel and Cannabis Research

- The Ministry of Health dedicated 8 million shekels a year for research
- Approved 150 research proposals
- 35 clinical trials.
- Over 50 U.S. companies conducting medical marijuana research in Israel
- invested more than \$125 million in Israeli cannabis operations

Set to Soar

Global medical marijuana could rise more than 300% in 10 years



Note: Billions of dollars
Source: Ameri Research

Bloomberg

Using Israel for FDA Approval

- Cannabis-based research program at Jerusalem's Shaarei Zedek hospital for Autism
 - Breath of Life Pharma plans to apply for “investigative new drug” status from the FDA
 - BOL has a cannabinoid clinical trial portfolio of 32 phase 2 trials
- Teva Pharmaceutical Industries, developed medical cannabis inhaler called Syqe
- PhytoTech Medical is developing an adhesive patch
- CannRx is developing a solution to convert cannabis smoke to a powder
- Sublingual tablets

Research Facilities

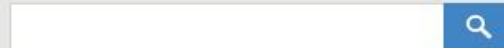
- Hebrew University in Jerusalem
- Tel Aviv University
- Steep Hill and iCan
- Breath of Life Pharma
- Protentional for US research partnerships





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CANNABINOID
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JOIN THE CANNABIS REVOLUTION

Cannabis is no longer just associated with **Getting High**
but is now tantamount to **Getting Healthy**

