Cann 10
The 2nd International
Medical Cannabis Conference
June 4-6, 2017
Dan Panorama Hotel, Tel Aviv, Israel

Cannabis on Trial

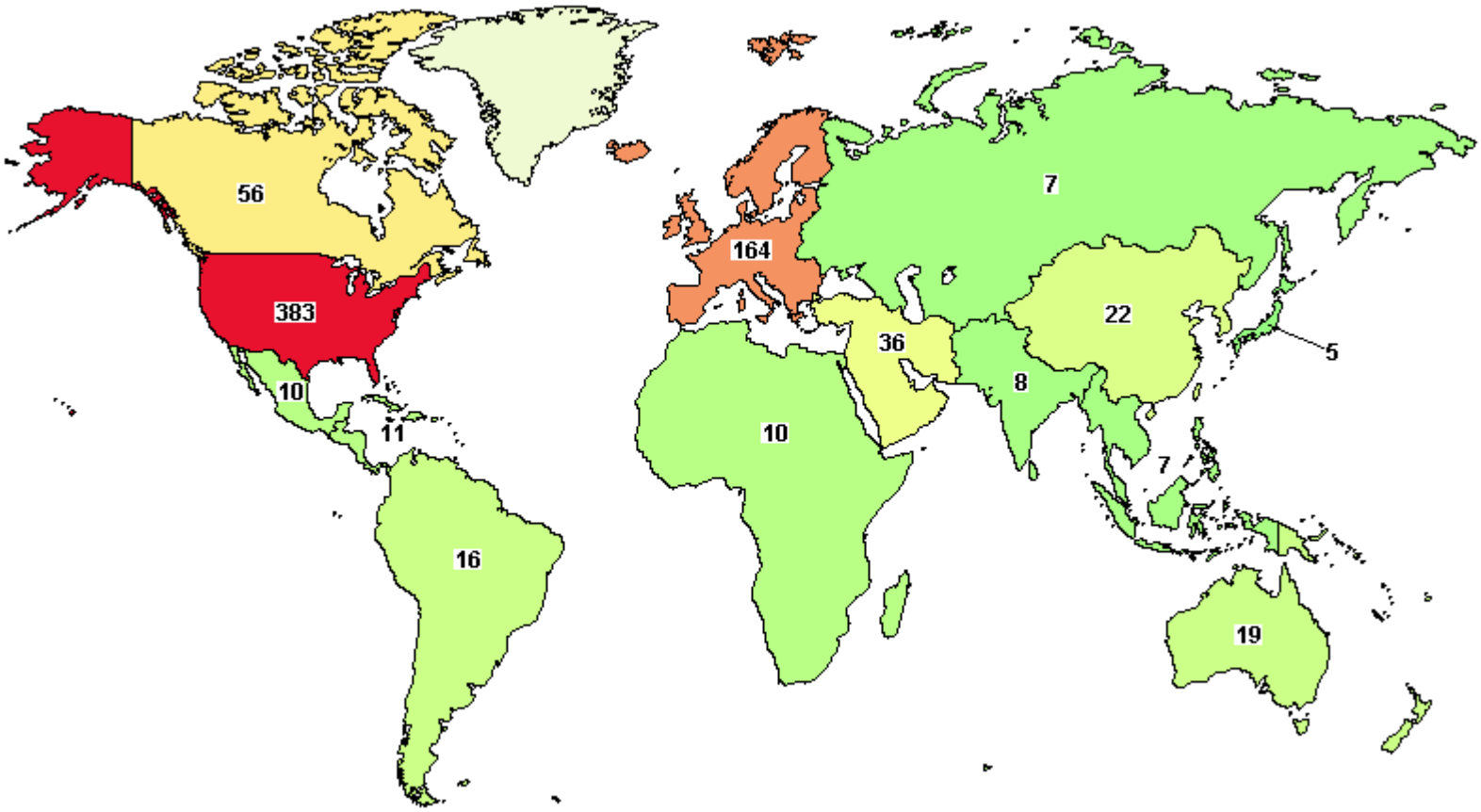
Clinical trials globally, focusing on Israel and the regulatory approval process

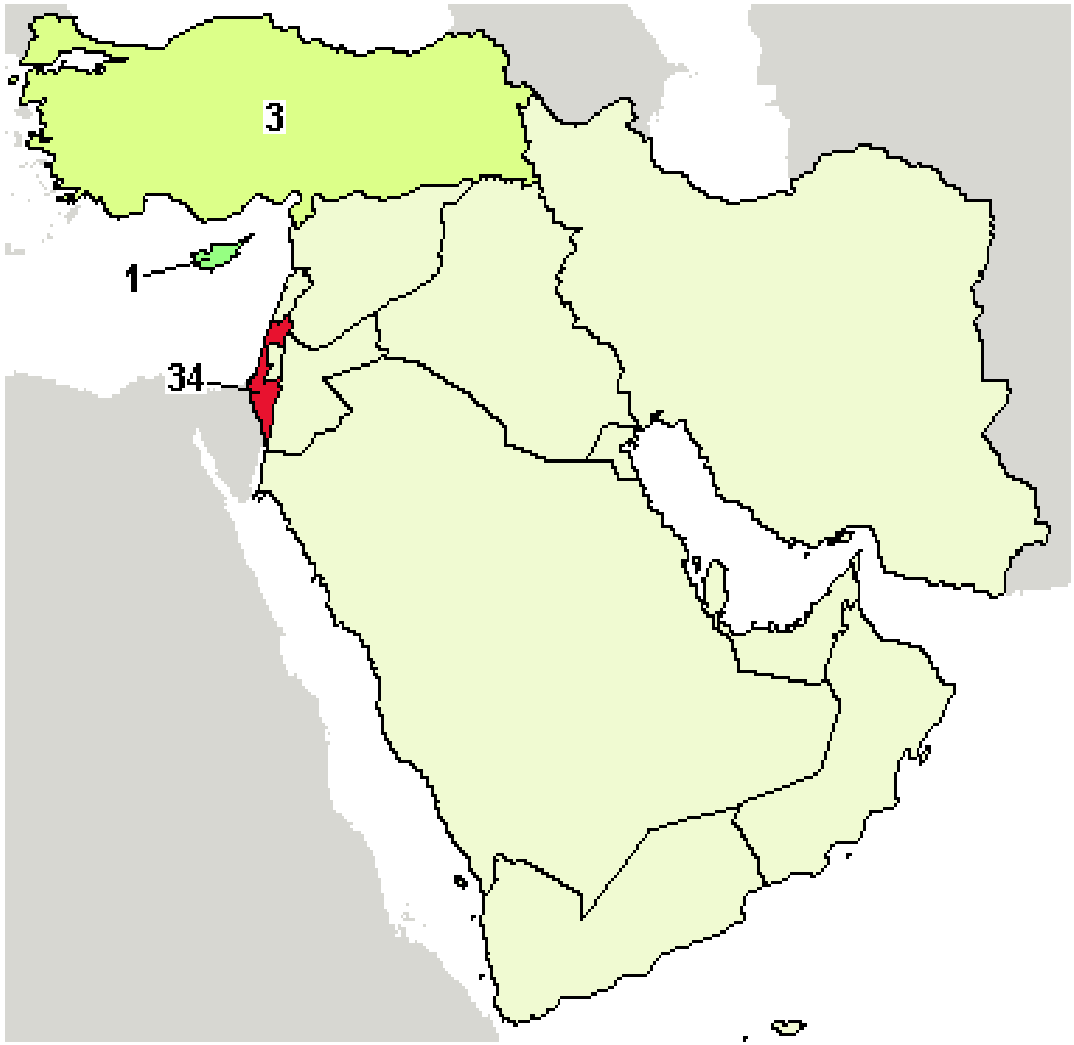
Disclosures

I (Stephen Levenstein) have no financial relationships to disclose concerning the content of this presentation or session

Where are Cannabis studies being done?

NIH – total 664 studies (clinicaltrials.gov)

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Therapeutic areas

- Pain – cancer , orthopedic
- Inflammatory bowel disease – Crohns and Ulcerative colitis
- Fibromyalgia
- Dystonia and spasticity
- Children with ASD and behavioral problems
- PTSD
- Tinnitus
- Anesthetic Premedication
- Graft vs Host Disorder
- Cancer cachexia and anorexia

FDA- Marijuana Research with Human Subjects

Several federal agencies involved

1. National Institute on Drug Abuse (NIDA)to obtain the marijuana for research

2. FDA – to submit an IND application for botanical drug products

3. Drug Enforcement Administration (DEA)to obtain investigator registration and site license to conduct studies with marijuana

FDA Process for Conducting Research with Marijuana

- Sponsor obtains pre-IND number from the FDA
- Sponsor contacts NIDA or other DEA registered source to obtain information of strains available to include in IND -CMC
- Sponsor contacts DEA for registration application and Schedule 1 license
- Sponsor obtains from NIDA – LOA to reference CMC information in NIDA's DMF(drug master file) on file with NDA
- Sponsor sends a copy of IND/Protocol plus LOA to FDA and DEA
- FDA reviews IND
- After FDA review and DEA registration Sponsor contacts NIDA or other DEA registered source to obtain marijuana

Israel MOH Medical Cannabis Unit

Cannabis is a substance that is defined as a “dangerous drug”. Medical Cannabis is not a medicine, it is not registered as a medicine, and its efficacy and safety when used for medical purposes has not yet been established. Nevertheless, there is evidence that cannabis could help patients suffering from certain medical conditions, and alleviate their suffering

The Medical Cannabis Agency is the authorized body in the Ministry of Health to issue patients with permits to use cannabis for medical purposes, in accordance with the Procedures that have been set (Procedure 106), to assess authorization and to issue appropriate permits to those engaged in the field of cannabis and to investigators and various research bodies that wish to carry out studies of cannabis and cannabinoids.

Israel MOH Procedure for Submission of an Application for a Cannabis Study

- Application for preliminary approval for feasibility to IMCA (Israeli Medical Cannabis Agency) ⇩ Copy to the clinical trials department.
- IMCA presents application to the Cannabis R and D Committee ⇩
- Application for clinical trial –medicinal preparation package submitted to Helsinki Committee ⇩
- Helsinki Committee submits to MOH 2 copies – Clinical Trials Dept, Medical Cannabis Agency ⇩
- IMCA approval ⇩
- Clinical Trial Unit –Form 8 ⇩
- Research Institute –Form 7 ⇩
- Investigator forward application for using cannabis for each subject license to IMCA

IMCA application

- Subject of the study
- Study procedures
- General description of three main aspects
  1. Professional status of submitting body and submitter.
  2. Advancement of medical, agricultural or industrial knowledge
  3. Meets the requirements for protecting public safety and prevents misuse

Investigator Brochure Contents

Subjects related to cannabis product

- Grower, growing site, manufacturer, factory , process, composition, COA
- Packaging , stability, supplier
- Concentrations, properties and characteristics of ingredients (THC, CBD others)
- Literature related to intended use

Informed Consent

- Waiver of medical confidentiality for receipt of a personal license
- Subject who did not have a cannabis license before the trial will not demand a license to continue after study period
- Undertakes to adhere to conditions of cannabis usage – use in presence of minors, prevention and reporting of theft
- Side effects – physiological , overdose, pregnancy
- Driving prohibition

Choosing a CRO

Serious business – Major Decision

CRO Selection Criteria

- Validated experience in targeted therapeutic area
- Robust data management and biostatistics capabilities
- IT system infra structure
- Appropriate human resource pool
- Experience in regulatory submission in markets of interest
- Validated technical facilities
- Relationship with outside vendors

CRO Selection Criteria – cont.

- Site management experience
- Openness to audits of infrastructure
- Clear roles and responsibilities
- Significant central laboratory experience
- Sound financial processes and invoicing
- Data protection
- Standard operating Procedures - SOPs

CRO Audit

References


"Although I'm sure she's a wonderful woman, it may be advisable to think of a referee other than your mother."
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Cost Savings

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