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Clinical And Non-Clinical Research In The Cannabis Space

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Disclaimers

*Co-Founder, Editor-in-Chief of Cannabis and Psychedelic Science Journal (CAPSJ) www.CAPSJ.com

*Principal Investigator of PBRC Site for LiBBY Study <https://libbystudy.org>

The goals for this presentation:

1. Brief outline of different types of research relevant to the cannabis space
2. Demystify what cannabis-related clinical research has been conducted since 2000
3. Give a first-hand account of realities conducting an NIH funded multi-site clinical trial with THC/CBD
4. Introduce "Cannabis And Psychedelic Science Journal (CAPSJ)"

General Aspects To Consider About Research



Peer-reviewed research **SHOULD** be the norm
and used for creating evidence-based approaches
and best practices for **EVERY** aspect of:

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Processes

Manufacturing
Testing
Cultivation
Processing

Product

Effects
Quality
Safety
*Customer satisfaction

Policy

Public health
State-Federal

SAID ANOTHER WAY



Processes

Manufacturing

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Policy

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State/Federal

Agencies

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Scientific Method

Observation

Testable question
(hypothesis)

Analyze to determine
if findings
occurred by chance

Retest, expand, or
move on based on
results

Peer Review to establish:
Best practices
Evidence-Based approach

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Drives the creation of:

- Credibility
- Standards
- Profitability
- Advocacy

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***Research/peer review is not esoteric, they are the only way to get to the other side**

Now Let's Talk About Challenges With Cannabis Clinical Research

- 1. Botanical drug**
- 2. Lack of awareness**
- 3. Schedule 1**

Botanical Drugs





U.S. FOOD & DRUG
ADMINISTRATION

Center for Drug Evaluation and Research (CDER)

A drug is a product that is intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans.

Botanical Drug:

- Consists of vegetable materials, which may include algae, macroscopic fungi, or combinations thereof.
- Available as (but not limited to) a solution (e.g., tea), powder, tablet, capsule, elixir, topical, or injection.
- Unique, complex mixtures, lack of a distinct active ingredient, and often with substantial prior human use.

*** Fermentation products and highly purified or chemically modified botanical substances are not considered botanical drugs.**

How many FDA approved drugs and medical devices are there?

How many FDA approved botanical drugs are there?

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> 19,000

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How many FDA approved botanical drugs are there?

2

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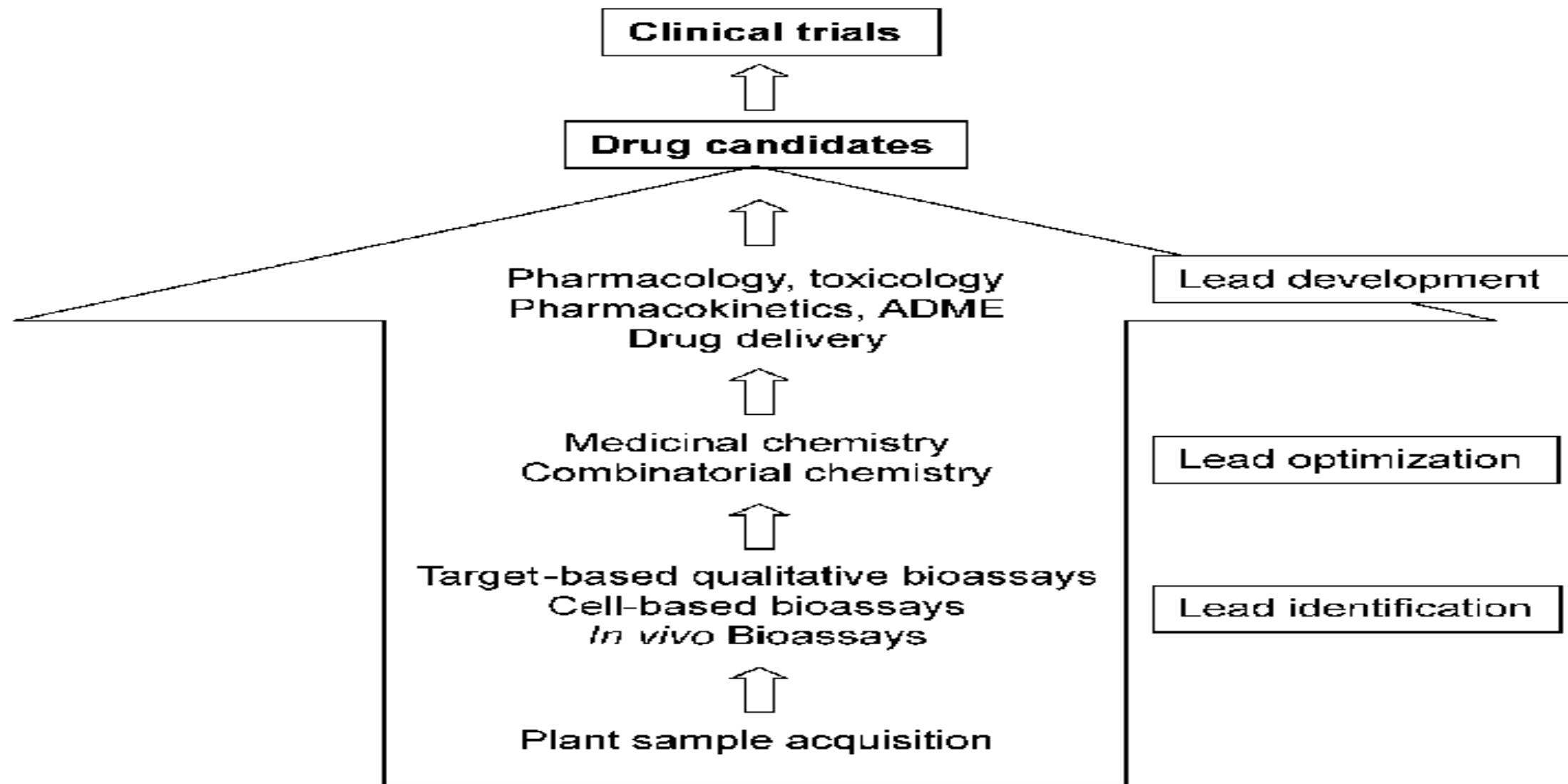
How many FDA approved botanical drugs are there?

2

No Cannabis Botanical Drugs

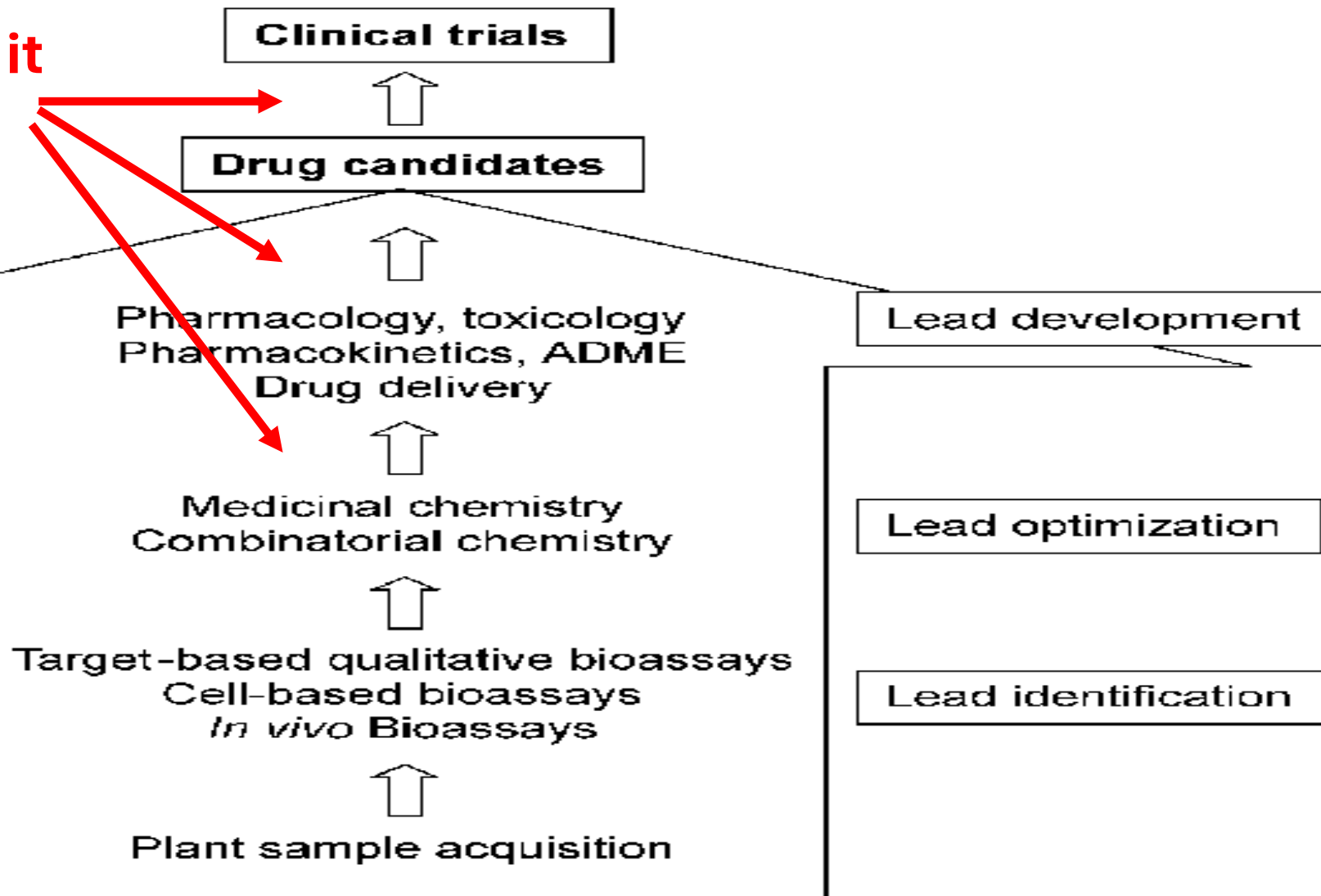
Epidiolex (CBD) and Dronabinol (THC) are not botanical drugs

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This is where it
falls apart



“It should be easier to develop drugs from plants as compared to chemically synthesized drugs”

“It should be easier to develop drugs from plants as compared to chemically synthesized drugs”

**Investigator
Brochure**

IND

Protocol

**Consent/HIPPA
Forms**

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4.0 PHYSICAL, CHEMICAL AND PHARMCEUTICAL PROPERTIES AND FORMULATION

Drug Substance Naming Conventions Molecular formulae, structural form and molecular mass
Formulation Storage and Handling

5.0 NONCLINICAL STUDIES

Nonclinical Pharmacology Mechanism(s) of Action Metabolism/Toxicology
Single-Dose Toxicology Genotoxicity Repeat-Dose Toxicology Carcinogenicity
Pre-Clinical studies Reproductive/Developmental Toxicity

6.0 EFFECTS IN HUMANS

Introduction Pharmacokinetics/ Pharmacokinetics Overdose
Absorption Distribution Metabolism Elimination
Safety/Efficacy Contraindications Warnings/Precautions Adverse Reactions
Abuse Potential Drug Interactions Marketing Experience

7.0 SUMMARY OF DATA AND GUIDANCE FOR THE INVESTIGATOR

Summary of Data Mechanism of Action Nonclinical Summary
Pharmacokinetics/Metabolism Clinical Safety Method of Administration Contraindications

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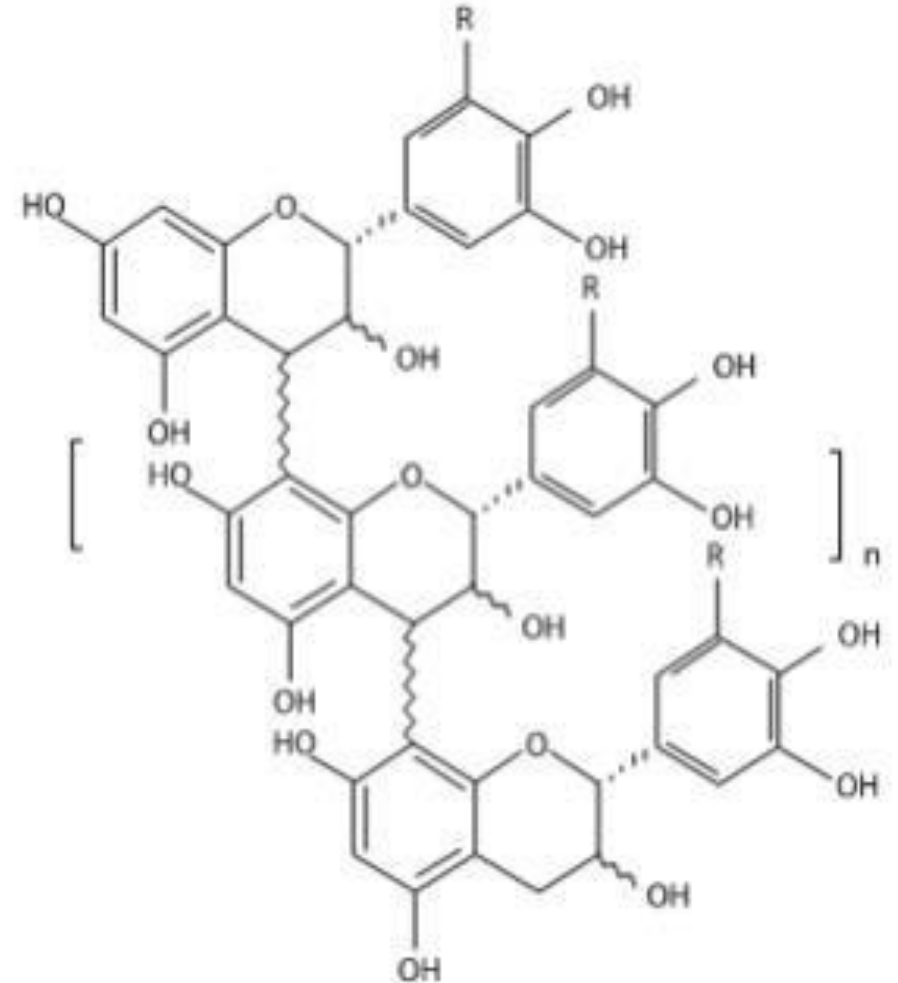
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MYTESI (crofelemer)

...is an oligomeric proanthocyanidin mixture **primarily composed of** (+)-catechin, (-)-epicatechin, (+)-gallocatechin, and (-)-epigallocatechin monomer units **linked in random sequence**...

---the average degree of polymerization for the **oligomers ranges between 5 and 7.5** as determined by phloroglucinol degradation.



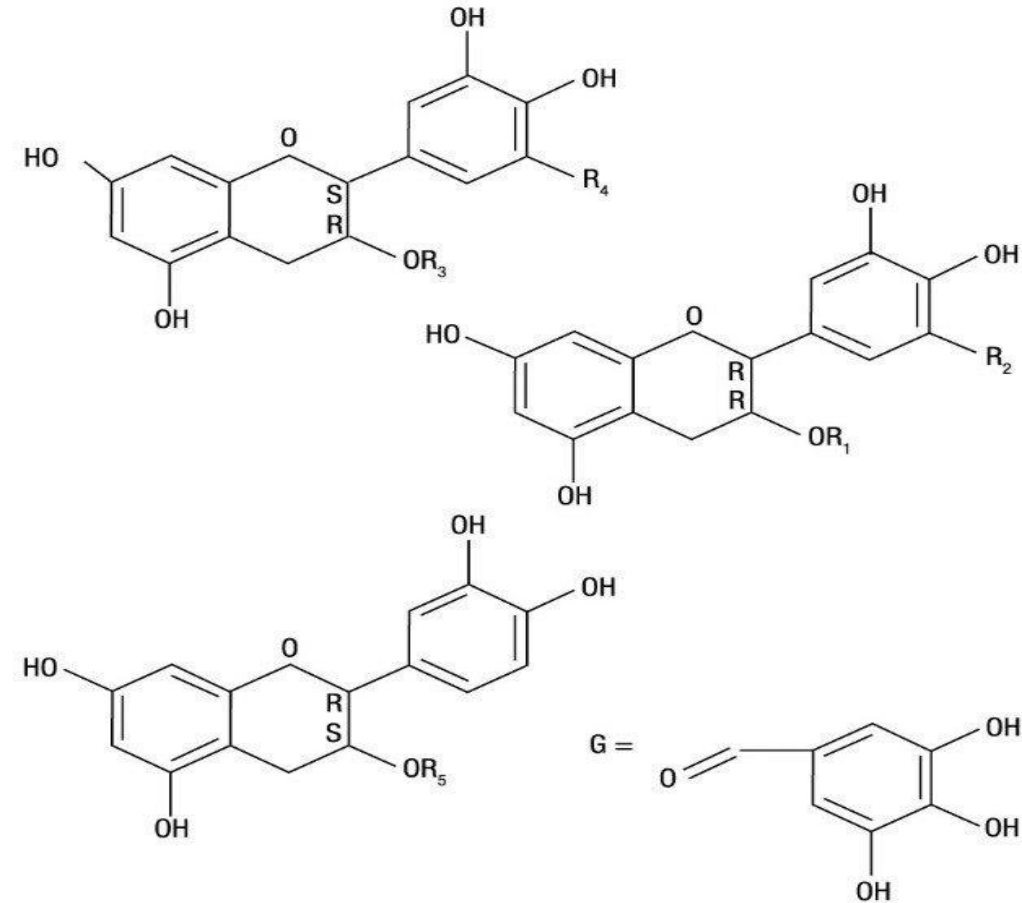
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Veregen[®]

....is a **partially purified fraction** of the water extract of green tea leaves from *Camellia sinensis* (L.)

....is a **mixture of catechins and other green tea components**...

....includes more than 55% of Epigallocatechin gallate (EGCg), Epicatechin (EC), Epigallocatechin (EGC), Epicatechin gallate (ECg), and some additional minor catechin derivatives.....**contains undefined botanical constituents derived from green tea leaves.**



Component	Abbrev.	R1	R2	R3	R4	R5
(-)-Epigallocatechin Gallate	(-)-EGCg	G	OH	-	-	-
(-)-Epicatechin Gallate	(-)-ECg	G	H	-	-	-
(-)-Epigallocatechin	(-)-EGC	H	OH	-	-	-
(-)-Epicatechin	(-)-EC	H	H	-	-	-
(-)-Gallocatechin Gallate	(-)-GCg	-	-	G	OH	-
(-)-Gallocatechin	(-)-GC	-	-	H	OH	-
(-)-Catechin Gallate	(-)-Cg	-	-	G	H	-
(+)-Catechin	(+)-C	-	-	-	-	H

Lack of awareness/misinformation

**Please see me to find out how to access this
publicly available info....**

How many cannabis-related studies in humans:

have been done (registered) since 2000?

are based in the USA?

are currently going on?

have results available/published?

are intervention studies versus observational studies?

have been funded by NIH versus industry sponsored?



How many cannabis-related studies in humans:

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917

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How many cannabis-related studies in humans:

have been done (registered) since 2000?

917

are based in the USA?

486

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How many cannabis-related studies in humans:

have been done (registered) since 2000?

917

are based in the USA?

486

are currently going on?

287

have results available/published?

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have been funded by NIH versus industry sponsored?

How many cannabis-related studies in humans:

have been done (registered) since 2000?

917

are based in the USA?

486

are currently going on?

287

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150

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have been done (registered) since 2000?

917

are based in the USA?

486

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150

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799

have been funded by NIH versus industry sponsored?

How many cannabis-related studies in humans:

have been done (registered) since 2000?

917

are based in the USA?

486

are currently going on?

287

have results available/published?

150

are intervention studies versus observational studies?

799

have been funded by NIH versus industry sponsored?

*245

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March 23, 2024

Not yet recruiting	73	218	NIH
Recruiting	165	27	Other Fed Agency
Active not recruiting	49	158	Industry
Completed	459	787	(individuals, universities, organizations)
Terminated	42		
?	129		

Phase 1	202
Phase 2	167
Phase 3	99
Phase 4	31
OTHER	418



For Studies with Results

Pharmacokinetics

Receptor kinetics

Appetite

Attention/Focus

Depression

Energy Level

Long Covid

Sleep

Motivation

Brain Imaging

Motor Function

Nausea

Pain in Brachial Plexus Injury, Cancer,
Neuropathy, fibromyalgia, menstruation,
Multiple Sclerosis, etc

Agitation in dementia

Essential Tremor

Parkinson's disease tremor

Cannabis used disorder

Epilepsy

Safety

Driving simulator

Cannabis use in pregnancy



Partial List of Companies Involved in Cannabis-Related Research

Advanced Brain Monitoring

Aelis Farma

Almirall, S.A.

Anebulo Pharmaceuticals

Aphios

Apurano Pharmaceuticals GmbH

Aurora Cannabis Inc

Bod Australia

Breath of Life International Pharma Ltd

Briev Agricultureal Crops Ltd

Canopy Growth Corp

Cannabics Pharmacueticals Inc

Cymra Life Sciences

Consumer Wellness Solutions

Endourage LLC

Fenix Innovation Group

Formula30A LLC

Hadassah Medical Org

IGC Pharma LLC

JAZZ Pharmaceuticals

Kite Systems

Klein Buendel Inc

LaSanta SAS

MGC Pharmaceuticals

Medlab Clinical

M.H MedicCane Ltd.

NextEvo Inc

Oculogica Inc

One World Cannabis
Ltd.

Phylos Biosciences Inc

Prairie Plan Systems Inc

Sahlgrenska University
Hospital

Sante Cannabis

Tetra Bio-Pharma

Tilray

TO Pharmaceuticals

Vertanical GmbH

SCHEDULE 1

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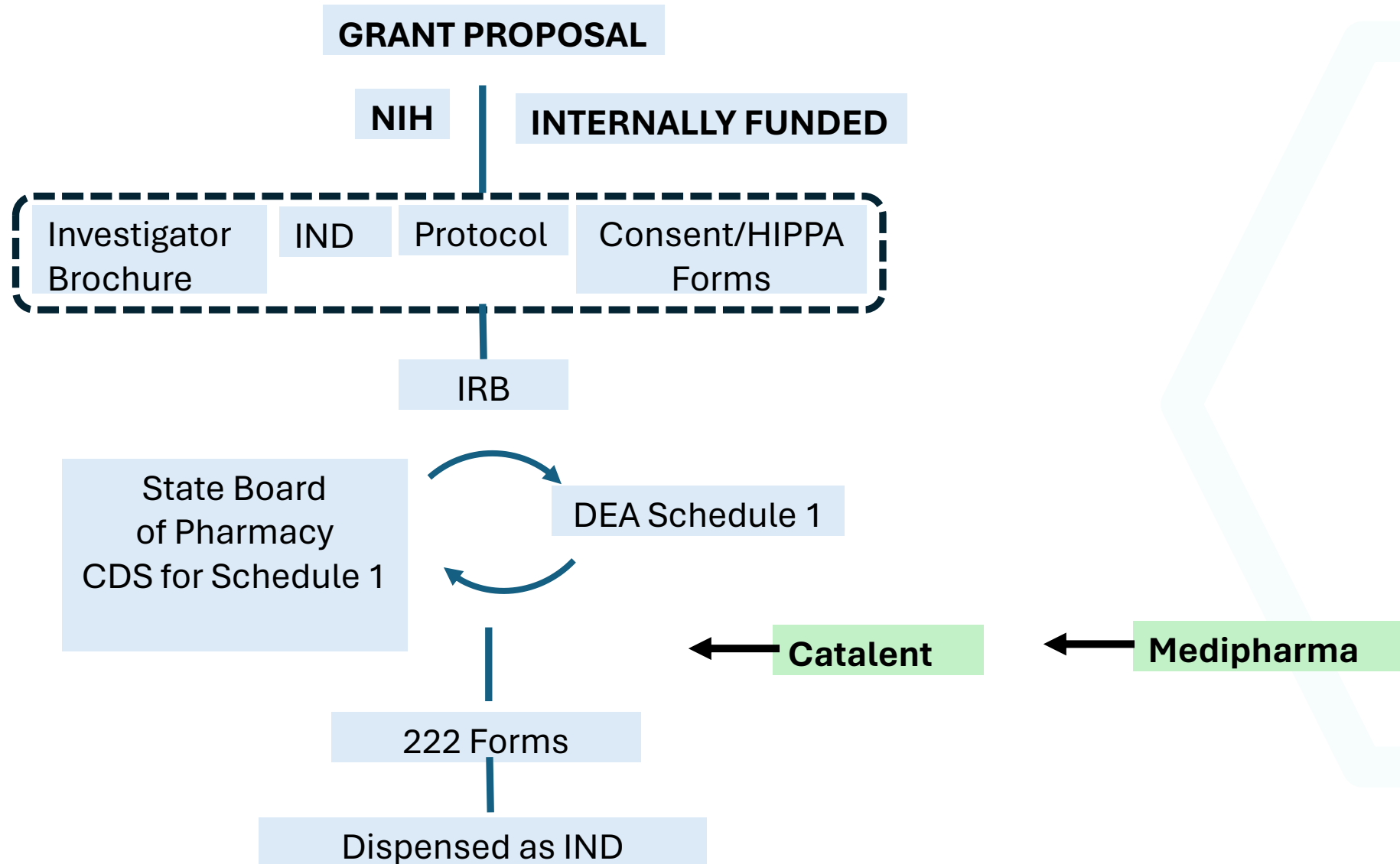
Life's end Benefits of cannaBidiol (CBD) and tetrahydrocannabinol (THC)



<https://libbystudy.org/>
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- NIH Funded
- 10 clinical sites
 - Medical Univ South Carolina
 - Georgetown Medical
 - Univ of Ky
 - Rush University
 - Banner Institute
 - Morehouse Medical
 - Pennington Biomedical**
 - Sun Valley Research Center
 - Univ of Maryland Medical
 - Vanderbilt University
- * One of largest and multisite
- 12-week intervention of THC/CBD versus placebo
- * Primary outcome agitation in hospice-eligible dementia patients'
- Laundry list of secondary outcomes

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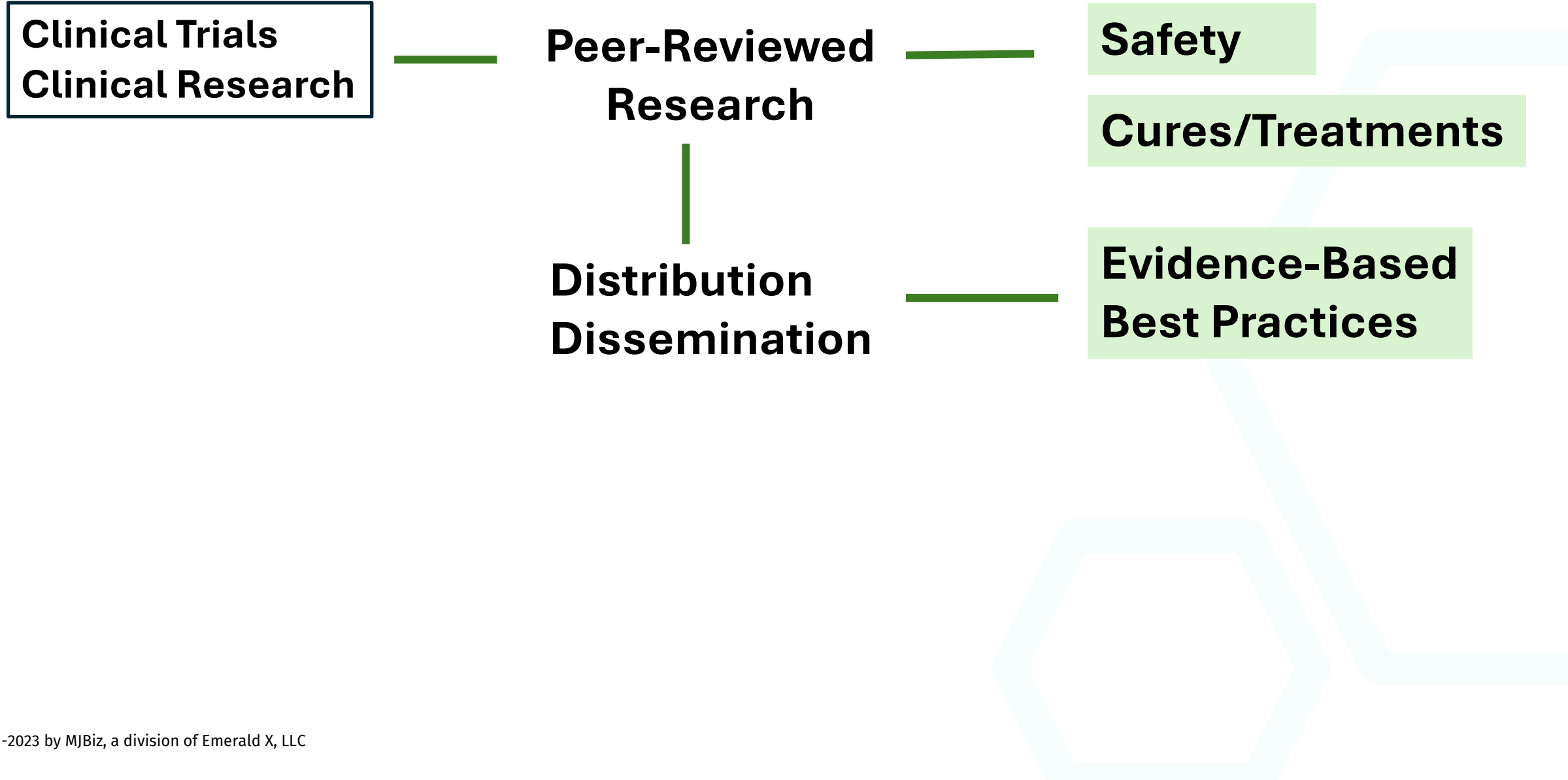


**Clinical Trials
Clinical Research**

**Peer-Reviewed
Research**

Safety

Cures/Treatments



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Clinical Trials Clinical Research

Processes

Manufacturing
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Policy

Public health
State/Federal Agencies

Peer-Reviewed Research

Distribution Dissemination

Safety

Evidence-Based Best Practices

ESTABLISH:

- Credibility
- Standards
- Profitability
- Advocacy

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**Clinical Trials
Clinical Research**

Processes

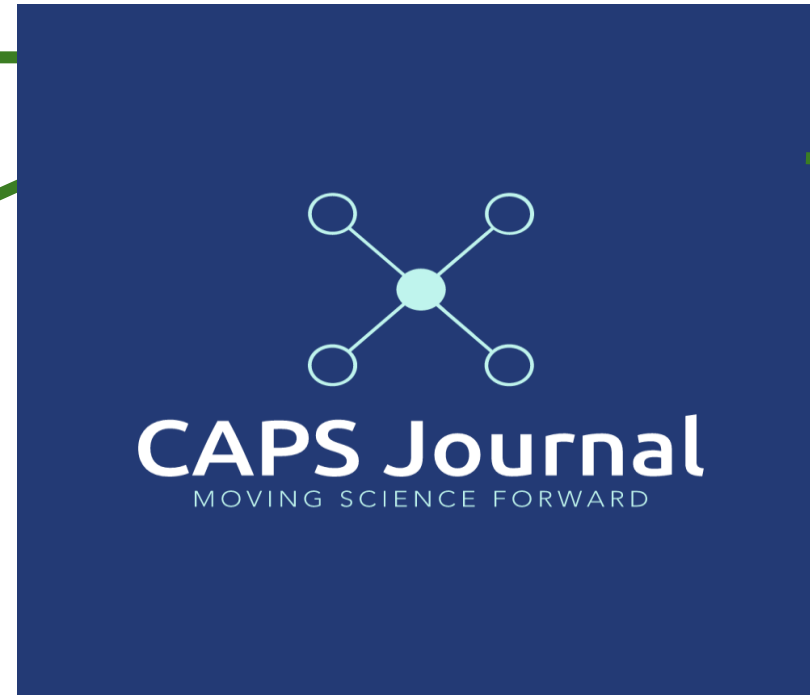
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www.capsj.com

Safety

Cures/Treatments

**Evidence-Based
Best Practices**

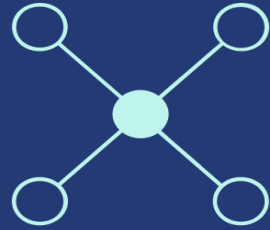
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Cannabis And Psychedelic Science Journal



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***Looking for distribution partners**

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	Pharmaceuticals	Medicinal Cannabis	Cosmetics	Dietary Supplements	Foods & Beverages
Health claims based on evidence of safety and efficacy in human clinical trials	✓	✗	✗	✗	✗
Safety and toxicology studies	✓	✗	✓ Dermal effects	✗	✗
Stability to establish shelf life	✓	✗ Varies by state	✗	✓	✗
Minimum purity requirements	✓ 98%+ typical	✗ Report %	✗ No prohibited ingredients	✓	✗
Control of impurities	✓ Monitored in every batch	✗ Varies widely by state	✓ Microbial contamination	✓	✗ List allergens on label
Batch-by-batch controls	✓	✓ Varies by state	✓	✓	✗
Premarket review by FDA	✓	✗	✗	✓ Notification of new ingredients	✗
Routine regulatory / quality inspections	✓	✓ Varies by state	✓	✓	✓
Validated methods / process /cleaning	✓	✓ Varies by state	✓	✓	✗
Production sanitation	✓	✓	✓	✓	✓
Documentation	✓	✓	✓	✓	✓
Complaint handling	✓	✗	✓	✓	✓
Packaging / labelling	✓	✓ Varies by state	✓	✓	✓