

Accelerating clinical and pre-clinical research opportunities in the cannabis space

Kyle Felling PhD, Paulo Gonzalez, Sha'keria Kelly, and Jeffrey N. Keller PhD*

Rapid Analytics™ , 131 Jeff Davis Boulevard, Natchez, MS 39120 C: 225-892-0464 E: jeff@rapidanalytics-ms.com

INTRODUCTION

Research involving cannabis and cannabis derivatives (CACD's) has been dramatically impaired by:

- Federal agency restrictions
- Lack of infrastructure
- Lack of awareness
- Fragmentation of the cannabis industry

The Marijuana and cannabidiol research expansion act (MCREA):

- Reduces federal agency barriers
- Allows physicians to discuss with patients
- Requires DEA to investigate benefits of CACD's
- Requires AG to ensure sufficient cannabis

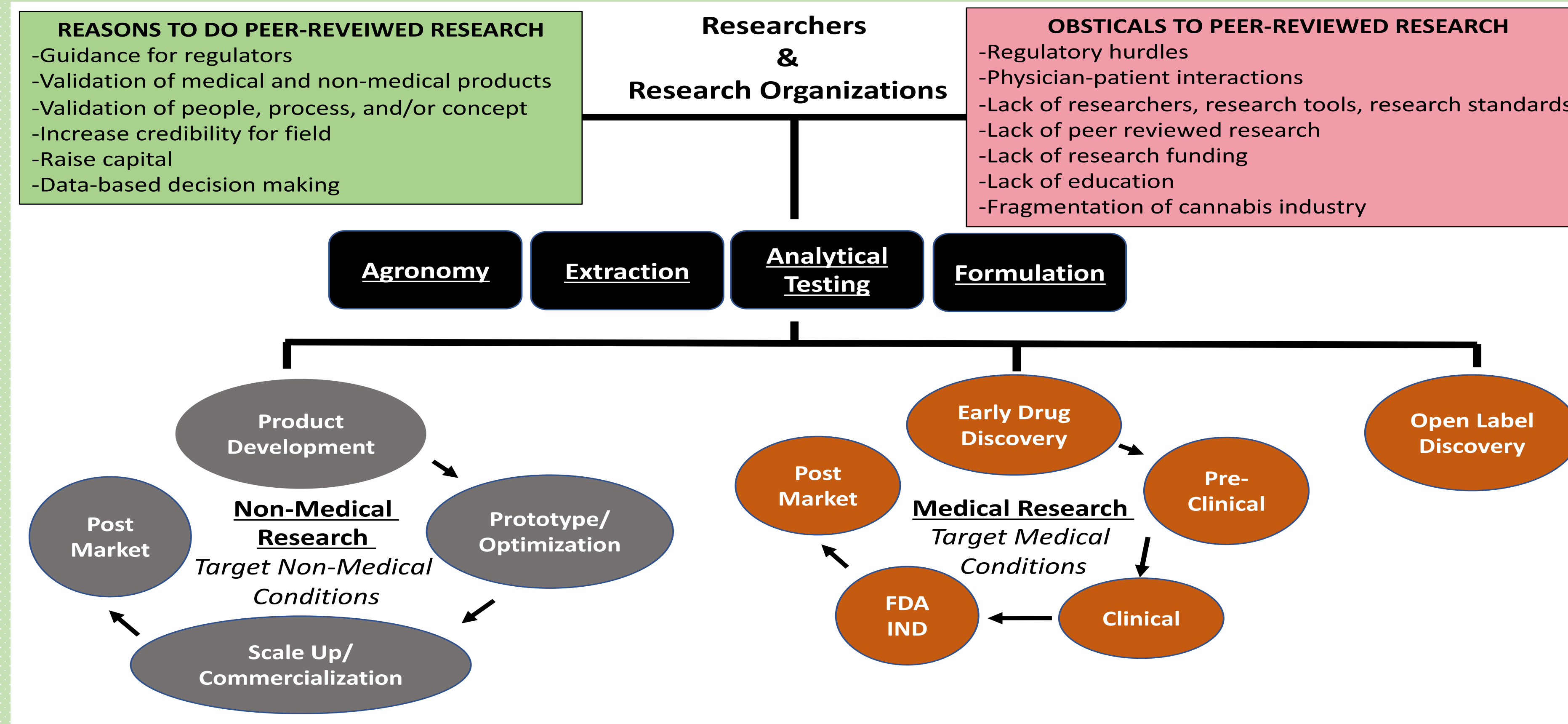
The MCREA will dramatically reduce federal restrictions related to CACD research.

The MCREA will not directly:

- Increase research infrastructure
- Heighten awareness
- Reduce industry fragmentation.

Improving cannabis-based research will require:

- Education
- Advocacy
- Innovation
- Collaboration
- Targeted Investment



REASONS TO DO PEER-REVIEWED RESEARCH

- Guidance for regulators
- Validation of medical and non-medical products
- Validation of people, process, and/or concept
- Increase credibility for field
- Raise capital
- Data-based decision making

OBSTACLES TO PEER-REVIEWED RESEARCH

- Regulatory hurdles
- Physician-patient interactions
- Lack of researchers, research tools, research standards
- Lack of peer reviewed research
- Lack of research funding
- Lack of education
- Fragmentation of cannabis industry

JUMPSTARTING CANNABIS RESEARCH

Increasing Peer-Reviewed Research

- Create Cannabis Focused Journals
- Enlist "Open-Access" Journals
- Educate on how to submit peer-reviewed research
- Educate on benefits of peer-reviewed research

Establish Infrastructure To Support Research

- Standardize terminology, methods, and data reporting
- Establish educational/training resources, databases, forums, and funding to support collaborative research.

Make Decisions Based On Peer-Reviewed Research

- Establishes broad credibility for the cannabis industry
- Validates plants, procedures, and products

Traditional Nutraceutical Development (Non-Medical)

1-12 Months \$ - \$\$\$ ~\$1,000 - \$50,000	1-12 Months \$ - \$\$\$ ~\$1,000 - \$100,000	2-24 Months \$\$ - \$\$\$\$ ~\$5,000 - \$200,000	1-8 Months \$ - \$\$\$ ~\$1,000 - \$100,000	Continual \$ - \$\$\$ ~\$1,000 - \$100,000
Conceptual Development of Nutraceutical	Pilot Development of Nutraceutical	Commercialization	Quality Assurance	POST-MARKET ANALYSIS
- Focus Groups - Literature Review - Brainstorming - Non-medical claims - Target customer	- Identification of initial ingredients - Initial Formulations - Prototype - Initial Scale up manufacture	- Testing/Optimization a. nutritional info b. shelf life (stability) c. packaging d. non-medical claims e. customer feedback	- Safety - Quality - Compliance - Performance	????

Traditional Drug Discovery (Medical Conditions)

< 6-12 Months \$ - \$\$ ~\$10,000 - \$250,000	6-24 Months \$\$ - \$\$\$ ~\$25,000 - \$500,000	6-96 Months \$\$\$ - \$\$\$\$\$ ~\$150,000 - < \$100M	1-8 Months \$\$\$ ~\$150,000 - \$1M	Continual \$\$ - \$\$\$ ~\$50,000 - \$1M
EARLY DRUG DISCOVERY	PRECLINICAL DISCOVERY	CLINICAL DISCOVERY	FDA REVIEW	POST-MARKET ANALYSIS
- Identify Target - Target Validation - High Throughput Screening - Identify Lead Molecules - Optimize Lead Molecules	- In vitro & Ex Vivo assays - Absorption, Distribution, Metabolism, Excretion (ADME) - Formulation, bioavailability -Dose-range -IND related studies -IND filing	- Phase I in safety healthy adults - Phase II-III in target population a. dosing b. safety-efficacy c. pharmacokinetics d. validation	- NDA - ANDA - BLA - FDA Approval - Drug Registration	FDA Adverse Event Reporting System (FAERS)



[Jeff@rapidanalytics-ms.com](mailto:jeff@rapidanalytics-ms.com)

<https://myrapidanalytics.com>