



# Developing cannabis-derived medicines

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**GW'S VISION** is to be the global leader in prescription cannabinoid medicines, developing and commercializing pharmaceutical products which address clear unmet needs





# Epidiolex – new treatment for rare epilepsies



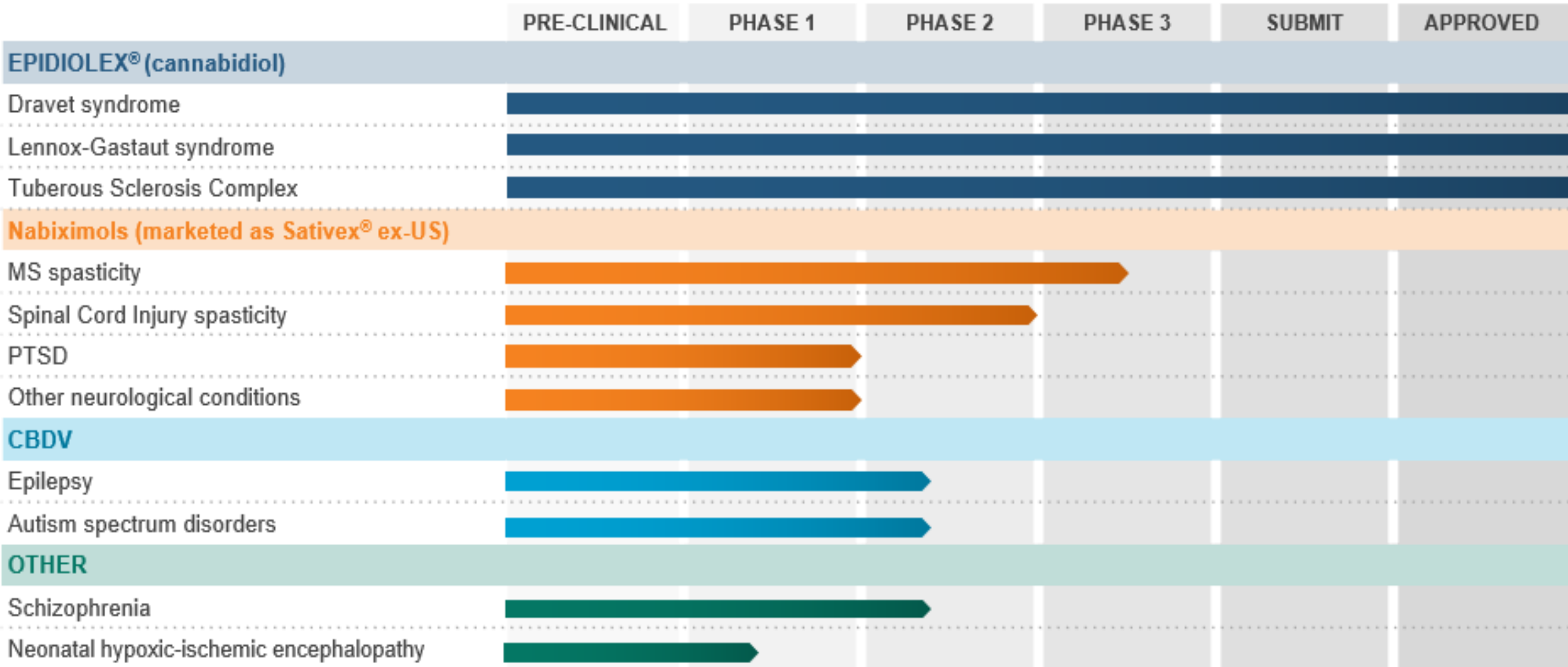
- > First and only plant-derived cannabinoid approved by FDA
- > First FDA-approved treatment in Dravet syndrome
- > First FDA-approved treatment since 2011 in Lennox-Gastaut syndrome



The NEW ENGLAND  
JOURNAL of MEDICINE

THE LANCET

# GW exploring a range of investigational cannabinoids for serious conditions



# Barriers to conducting rigorous scientific and medical study necessary to support FDA approval of cannabis-based medicines

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- The costs and burdens associated with clinical development of FDA-approved drugs.
- Most cannabis is still a schedule I controlled substance under the federal Controlled Substances Act, which significantly increases cost burdens.
- The proliferation of competing, unapproved products, which have little or no development costs prior to their marketing and do not follow the exacting manufacturing standards that FDA requires for approved medicines.
- Unique intellectual property challenges that may affect compounds derived from nature.



**Quality, Safety and Efficacy**

45 acre / 18 hectare glasshouse  
Material to supply 36,000 children for one year



20 acre / 8 hectare glasshouse across 2 locations  
Material to supply 18,000 children for one year

## Epidiolex commercial growing site Norfolk/East and Yorkshire/North



# Epidiolex manufacturing process—drug substance

## DRUG SUBSTANCE

CBD Botanical Raw Material

Milling

Decarboxylation

CO<sub>2</sub> Extraction

CBD Botanical Drug Extract (Crude Form)

Multi-step Crystallisation

Pure CBD



CO<sub>2</sub>  
Extraction



Filtration &  
Drying



# Epidiolex manufacturing process—drug product

## DRUG PRODUCT

**CBD Pure**

Bulk Solution Production (GW)  
Sesame Oil/Ethanol

Filling and capping  
(GW)

**Product labelling and packaging**

Labelling, Check weigh, Tamper Evidence,  
Serialization (GW)

**Epidiolex**



Filling line

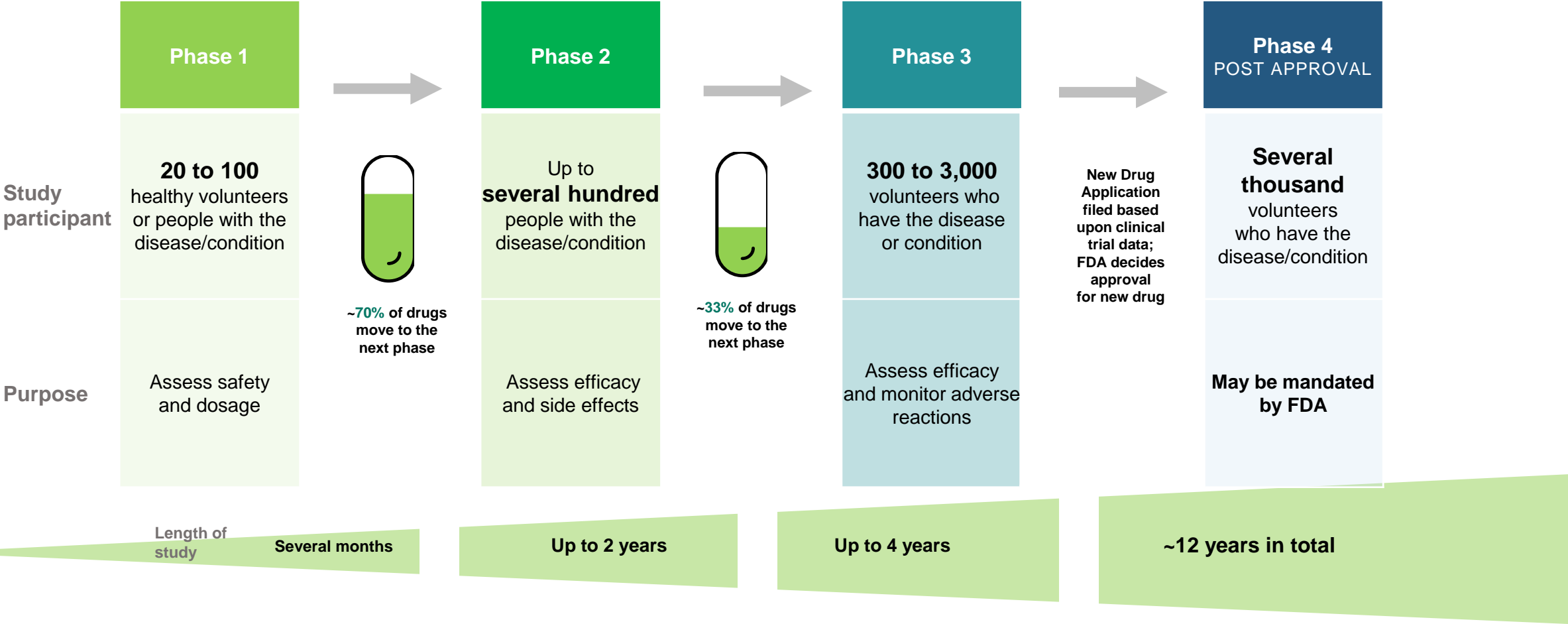


Labeling and  
packaging  
line

# Safety and Efficacy

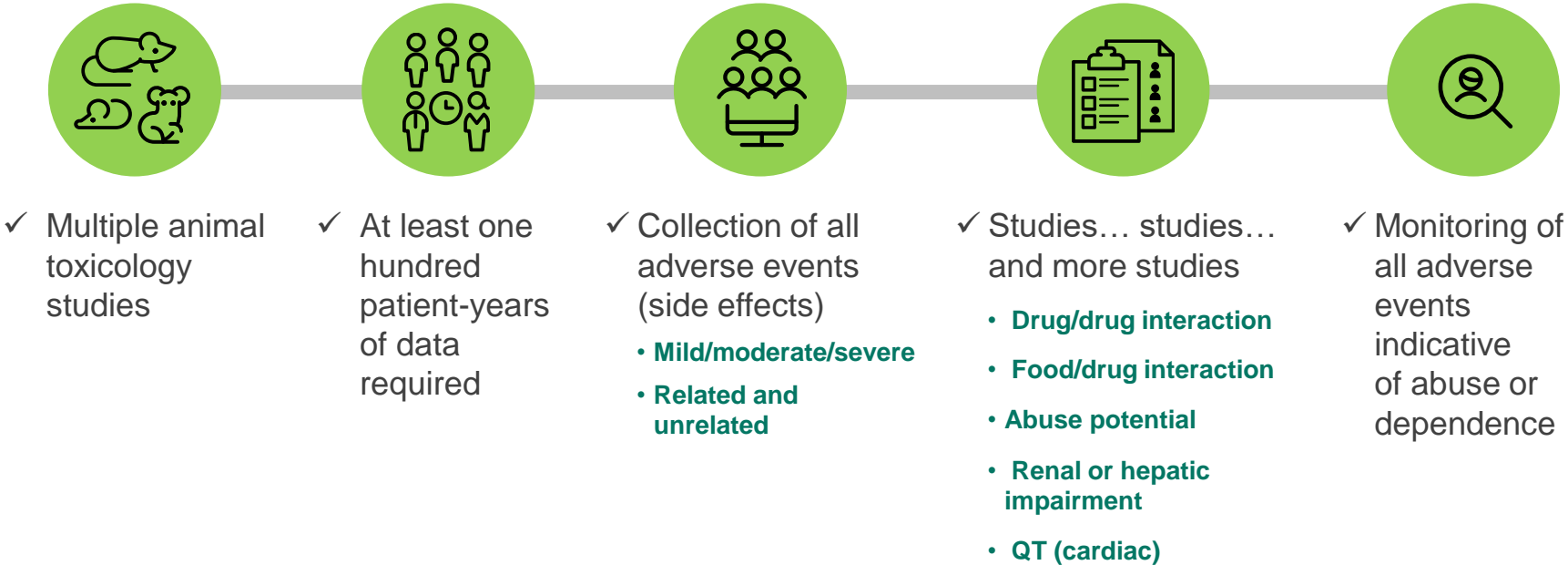


# What differentiates an FDA-approved cannabis-derived medicine?



The drug development process: <https://www.fda.gov/ForPatients/Approvals/Drugs/ucm405622.htm>. Accessed August 30, 2017.

# What additional studies must be done to show that medicines are safe?



# Cannabis use is associated with adverse health effects

- The National Academies of Sciences, Engineering and Medicine found cannabis use is associated with changes in brain structure;<sup>1</sup> development of psychoses;<sup>2</sup> and lower birth weight for children born to mothers using cannabis during gestation.<sup>3</sup>
- In 2019, the US Surgeon General issued a rare health advisory warning the public of the risks of cannabis use among pregnant women and adolescents.<sup>4</sup>
- Recent research indicates cannabis use can drive cancer growth in certain types of head and neck cancer;<sup>5</sup> increase the risk of heart attacks<sup>6</sup> and strokes;<sup>7</sup> and impair heart functioning.<sup>8</sup>

<sup>1</sup> Brumback, T., N. Castro, J. Jacobus, and S. Tapert. 2016. Effects of marijuana use on brain structure and function: neuroimaging findings from a neurodevelopmental perspective. *International Review of Neurobiology* 129:33–65. <https://health.ucsd.edu/news/releases/Pages/2020-01-13-how-cannabis-accelerates-growth-of-hpv-related-head-and-neck-cancer-identified.aspx>.

<sup>2</sup> Marconi, A., M. Di Forti, C. M. Lewis, R. M. Murray, and E. Vassos. 2016. Meta-analysis of the association between the level of cannabis use and risk of psychosis. *Schizophrenia Bulletin* 42(5):1262–1269.

<sup>3</sup> Gunn, J. K. L., C. B. Rosales, K. E. Center, A. Nunez, S. J. Gibson, C. Christ, and J. E. Ehiri. 2016. Prenatal exposure to cannabis and maternal and child health outcomes: A systematic review and meta-analysis. *BMJ Open* 6(4):e009986.

<sup>4</sup> <https://www.hhs.gov/surgeongeneral/reports-and-publications/addiction-and-substance-misuse/advisory-on-marijuana-use-and-developing-brain/index.html>

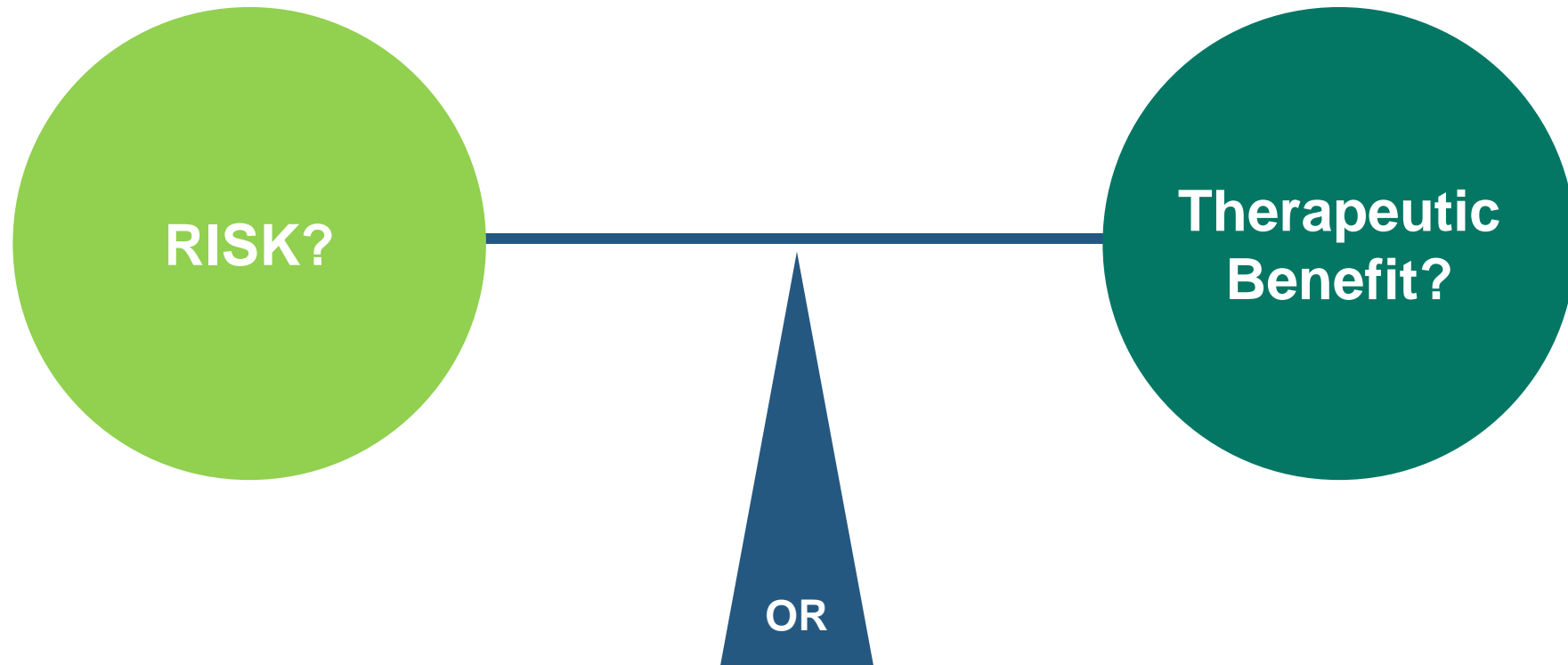
<sup>5</sup> Patel R, et al, Cannabis Use is an Independent Predictor of Acute Myocardial Infarction Hospitalization in Younger Population, *Journal of Adolescent Health*. 2020. Vol. 1, issue 1.

<sup>6</sup> Parekh T, Pemmasani S, Desai R, Cannabis Use Among Young Adults (18–44 Years of Age) and Risk of Stroke, *Stroke*. 2019. Vol 51, No. 1.

<sup>7</sup> Khanji M, et al, Association Between Recreational Cannabis Use and Cardiac Structure and Function, *JACC Cardiovascular Imaging*. 2019. Vol. \_\_, No. \_\_.

# Balance of benefit and risk

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## Food & Drug Administration (FDA)-Approved Cannabinoid Products<sup>1,2</sup>

### *Plant-Based and Synthetic Medicines*

#### Study Evidence & Requirements

- ✓ Studied in placebo-controlled, clinical trials

#### Manufacturing

- ✓ Produced and federally inspected to ensure good manufacturing practices (cGMP) while adhering to strict specifications that ensure batch consistency and stable shelf life

#### Quality Standards

- ✓ Meets FDA standards for quality, stability, consistency

#### Legality

- ✓ Federally legal as prescribed; similar to other DEA-controlled prescription medicines

#### Coverage

- ✓ Can be eligible for insurance coverage

The FDA  
“Gold  
Standard”  
and the  
hallmarks  
of an FDA-  
approved  
medicine

1. <https://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143534.htm>. Accessed October 31, 2017.

2. <https://www.fda.gov/downloads/Drugs/.../Guidances/ucm073497.pdf>. Accessed October 30, 2017.





*Thank you*