

Patient Insights and Real-World Data from Social Media

Dr. Regenold GmbH

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About Us

- Founded in 1994 by Dr. Jürgen Regenold
- Initial focus on clients wishing to access the German market
- Increased international scope of projects
- Extended regulatory advice to drug development projects
- Expanded geographically and established the international network, regulanet® in 2001, which today covers more than 90 countries with over 180 experts
- Started developing our presence in data science and analytics in 2015
- Currently establishing a validated AI platform (according to GAMP), for the development of solutions in the GxP and Medical Device area
- Today the Regenold Group has ~100 employees

Agenda

1. Application Areas
2. An example case study- PV
 1. Why do it?
 2. Project Phases
 3. Outputs 'Dashboard'



Social Media Analysis: Application Areas

- **Marketing/Market Access**
 - Product development
 - Product positioning
 - Competitive insights
- **Portfolio and Product Lifecycle Management**
- **Med Tech**
 - Post Market Surveillance
 - Post Market Clinical Follow-up
- **Drugs**
 - Pharmacovigilance
- **Food Supplements**
- **Cosmetics**

An example from Pharmacovigilance point of view: Social Media Analysis using the example of cannabis flowers for medical use

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Social Media Analysis – why?

FDA Patient-Focused Drug Development



PATIENT-FOCUSED DRUG DEVELOPMENT
PUBLIC WORKSHOP ON GUIDANCE 1

COLLECTING COMPREHENSIVE AND REPRESENTATIVE INPUT

DISCUSSION DOCUMENT

Workshop Date: December 18, 2017

FDA encourages external stakeholders to explore the use of social media tools (e.g., medical community blogs; crowdsourcing; social media pages, such as Twitter, Facebook, etc.) to shed light on patients' perspectives regarding symptoms and impacts of a disease or condition.

FDA recommends that social media data be used as a complementary supplement to other traditional qualitative data sources (e.g., literature, interviews, or expert opinion).

Social Media Analysis – how?

When people with no medical background talk about their illnesses and treatments online, they generate mountains of unstructured data.



If you want actionable insights, you're going to need serious automation, and, crucially, powerful analytics.

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project phases: medical cannabis

Data Collection

- Initial twitter analysis was performed for three months and consisted of 10230 posts. After removal of duplicates 6937 posts remained.
- Potential additional data sources are reddit, medchat, drugs.com

Which sources of social media are selected for the analysis?

Annotate

- A team of 5 annotators manually annotate posts according to their quality, relevance and information content
- Establishing the basics for training our models

Manual annotation of posts

Model & Predict

- This step includes
 - data preparation
 - model training
 - building rules in SAS VTA
 - model deployment

Models are developed

Build Dashboard

- Findings from social media are loaded to a dashboard
- An interface to facilitate visualization, exploration and reporting of trends on social media in SAS Visual Analytics is designed
- If required, the client can get a tailored report

Making the results visible

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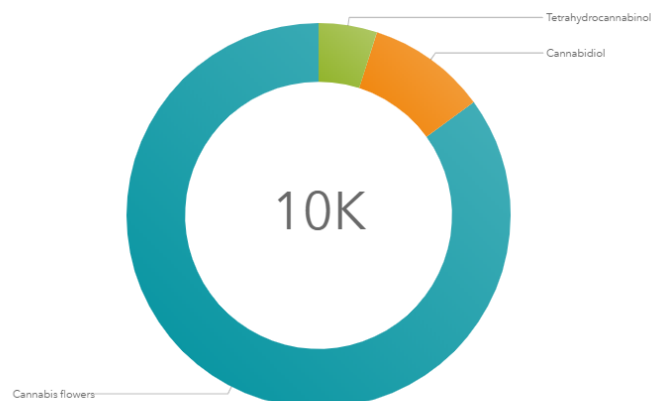
Outputs ‘Dashboard’

Examples of a social media analysis of
medical cannabis

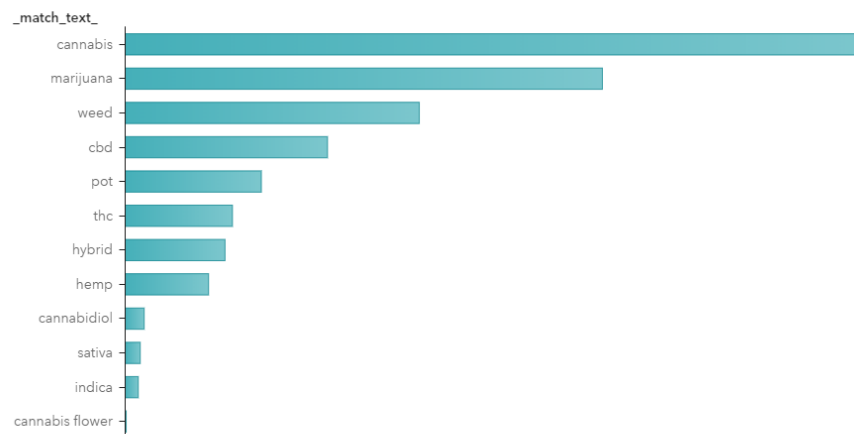
Social Media Analysis Dashboard

The report consist of the results of analysis of data from Twitter for Medical Cannabis. The analysis includes the Adverse Events, Indications and preferred route of administration for Cannabis.

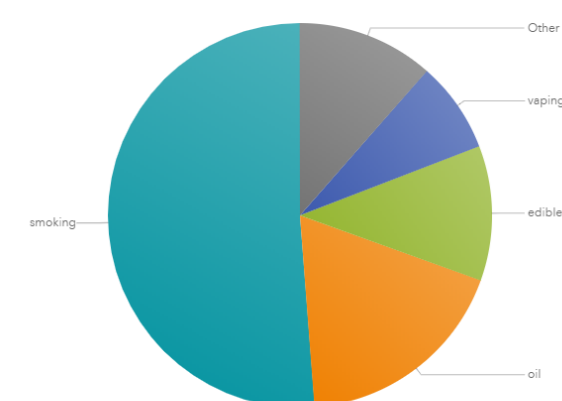
Frequency of Drugs



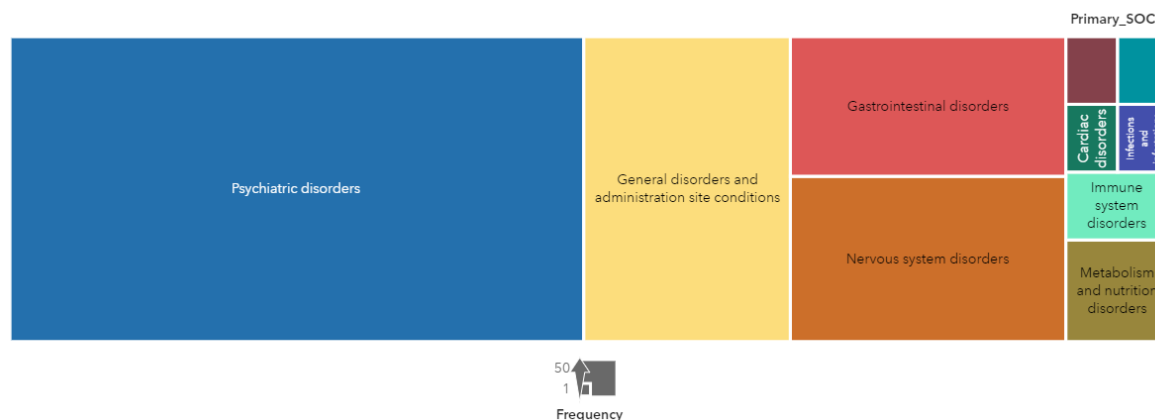
Cannabis Tweet Terms



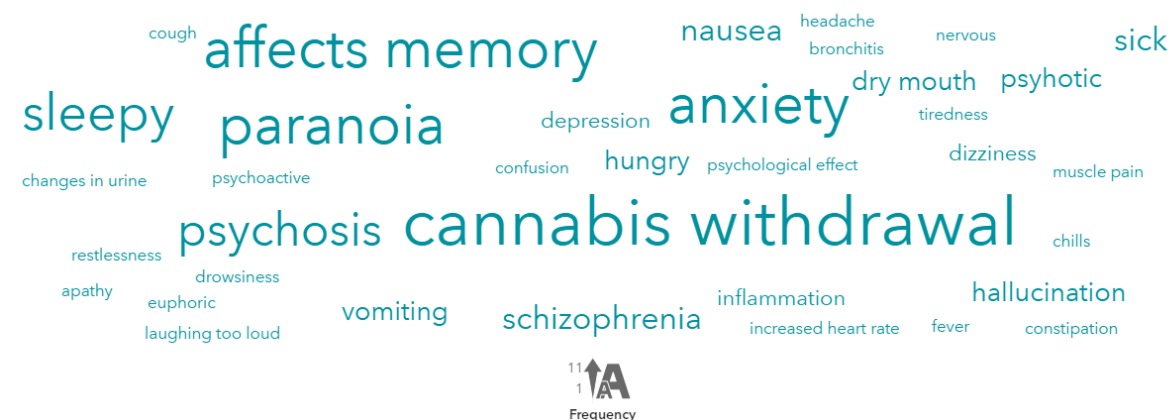
Route of Administration



Primary SOC Term Frequency of Adverse Events

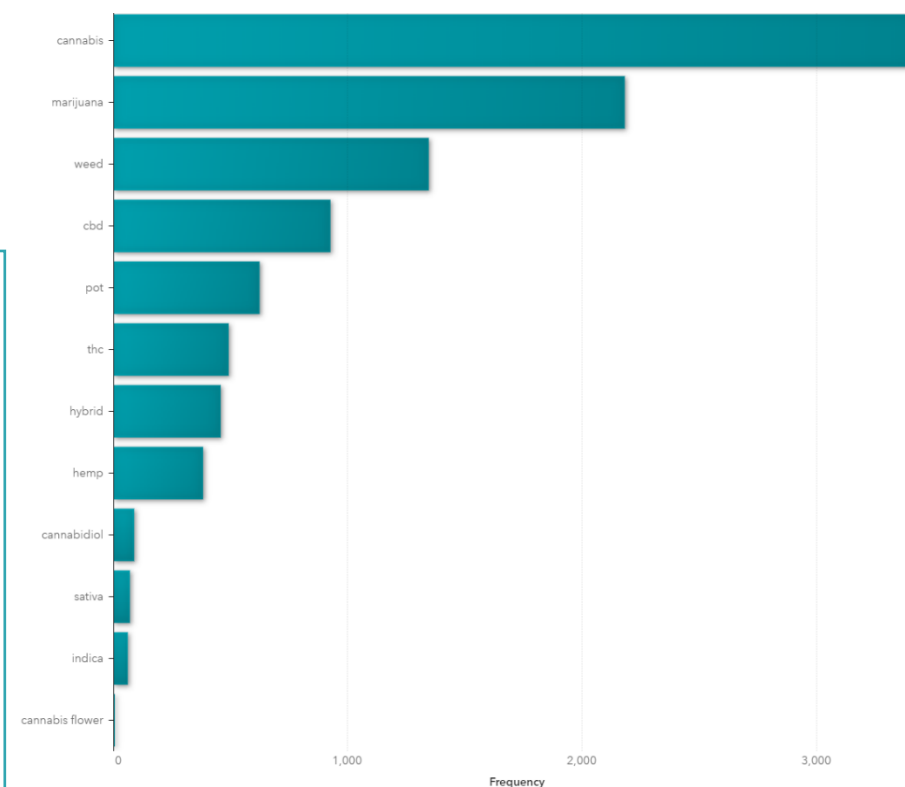
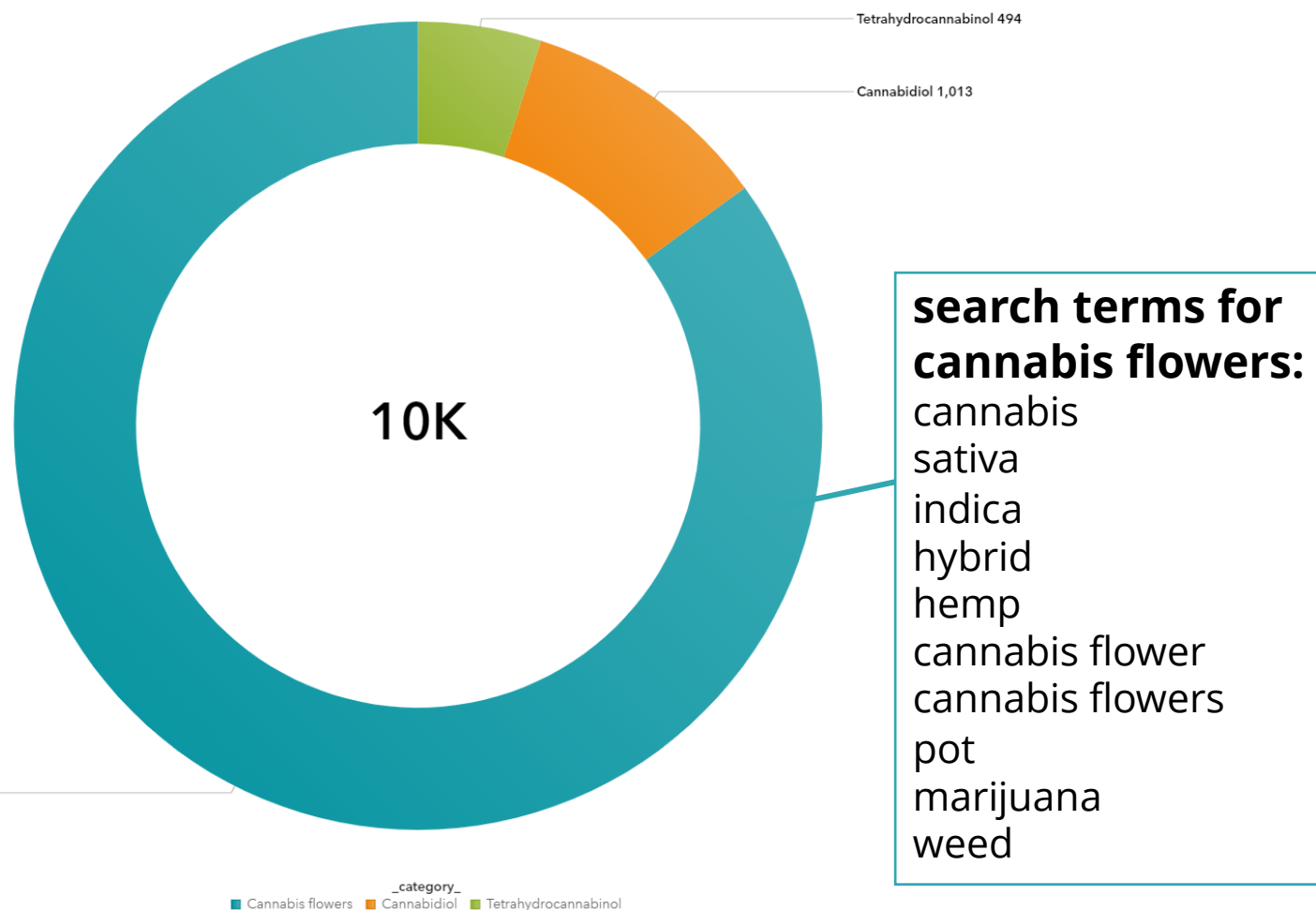


Word Cloud of Adverse Events Terms



Substances commonly talked about

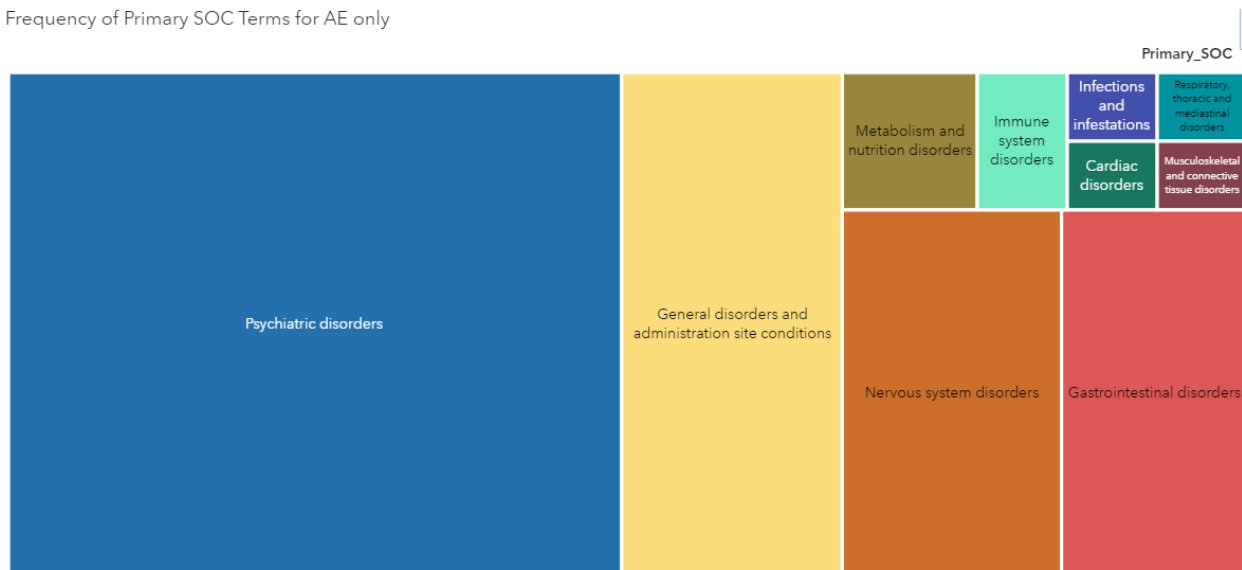
Frequencies of posts about cannabis flowers and cannabinoids



10230
106

Overview dashboard for adverse events

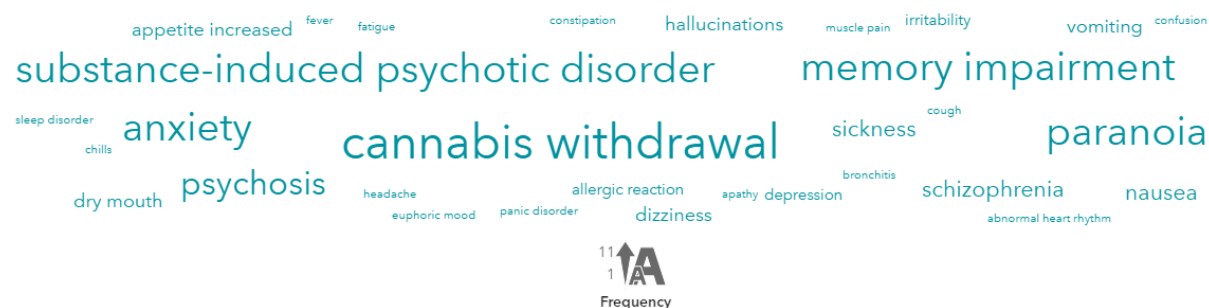
Frequency of Primary SOC Terms for AE only



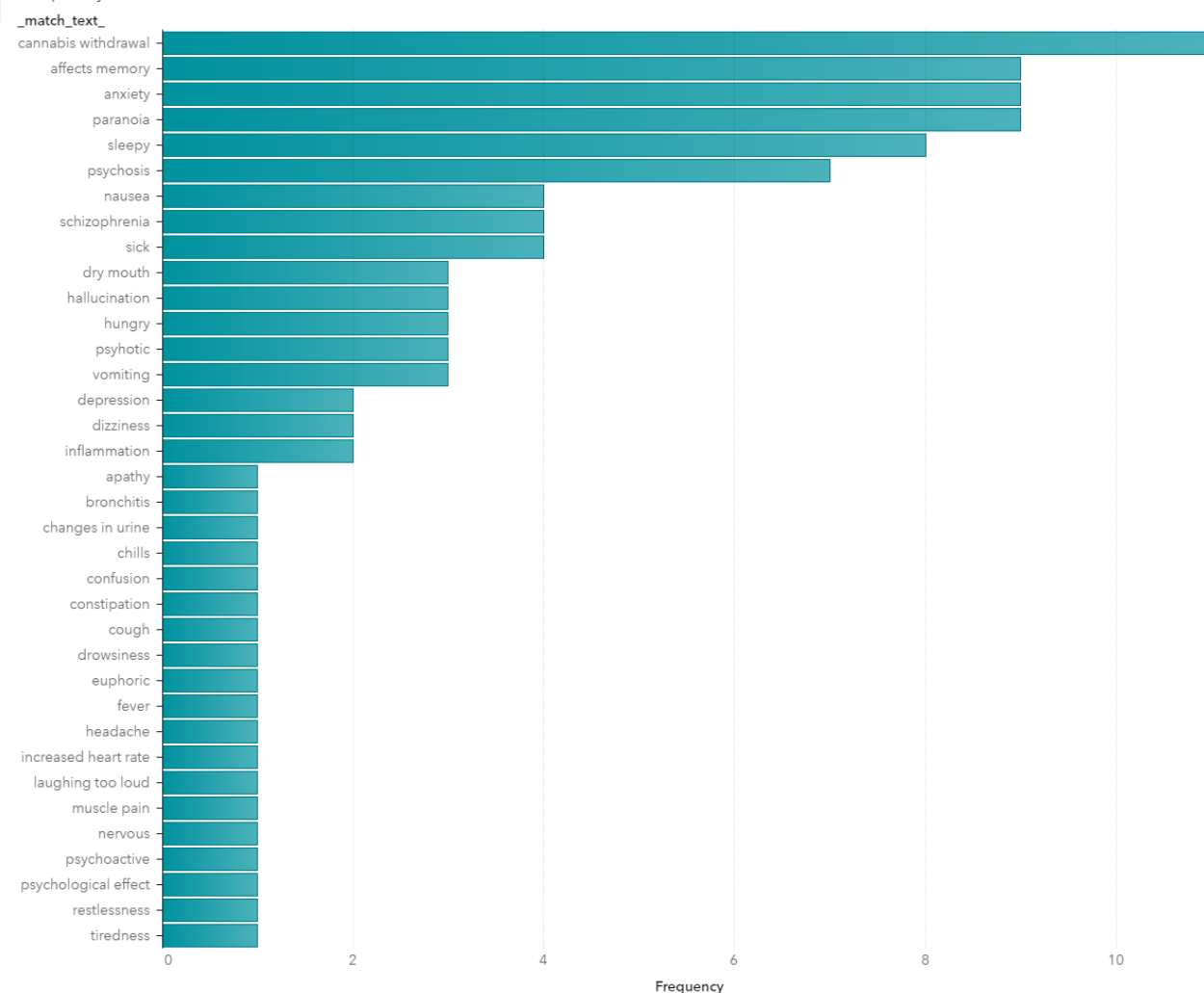
all AE terms were mapped to SOC terms in MedDRA

50
1
Frequency

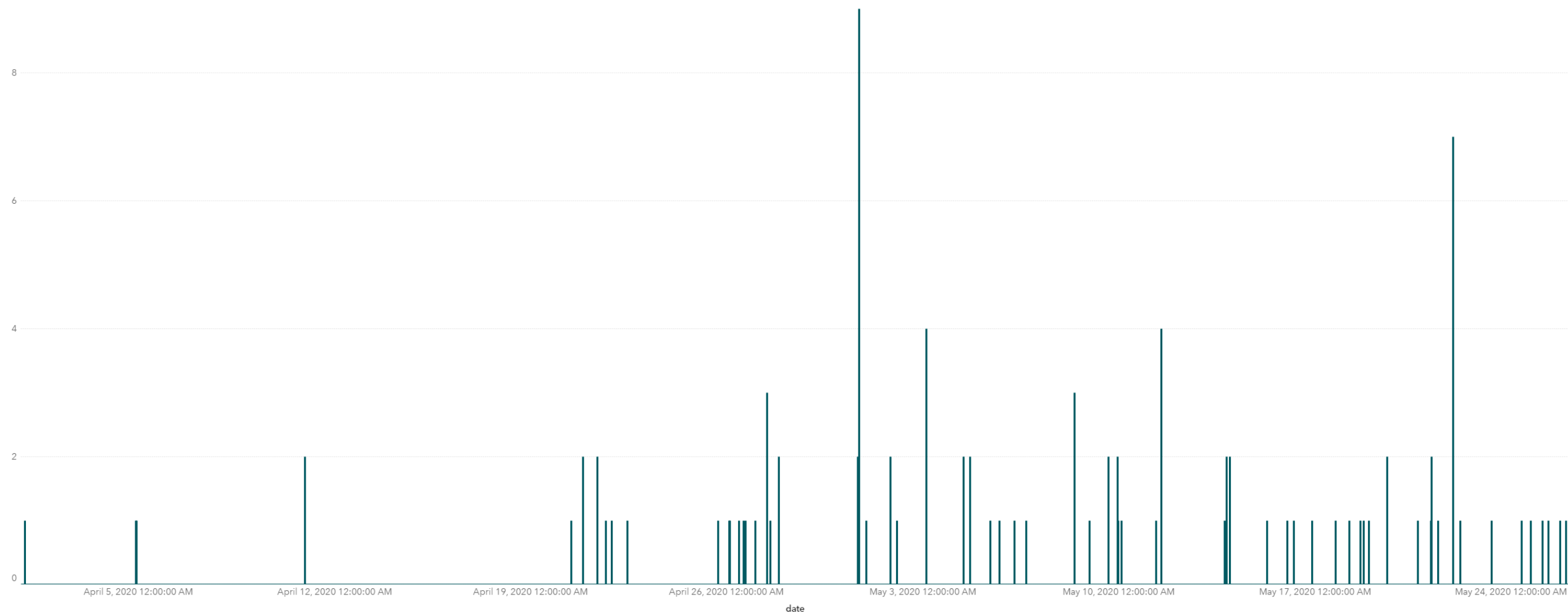
Frequency of LLT_Terms



Frequency Percent of Adverse Event Terms



Frequency of adverse event posts over time



Adverse events – PIL/SmPC category vs. pareto analysis

SmPC of Cannabis, dried flowers



VS.

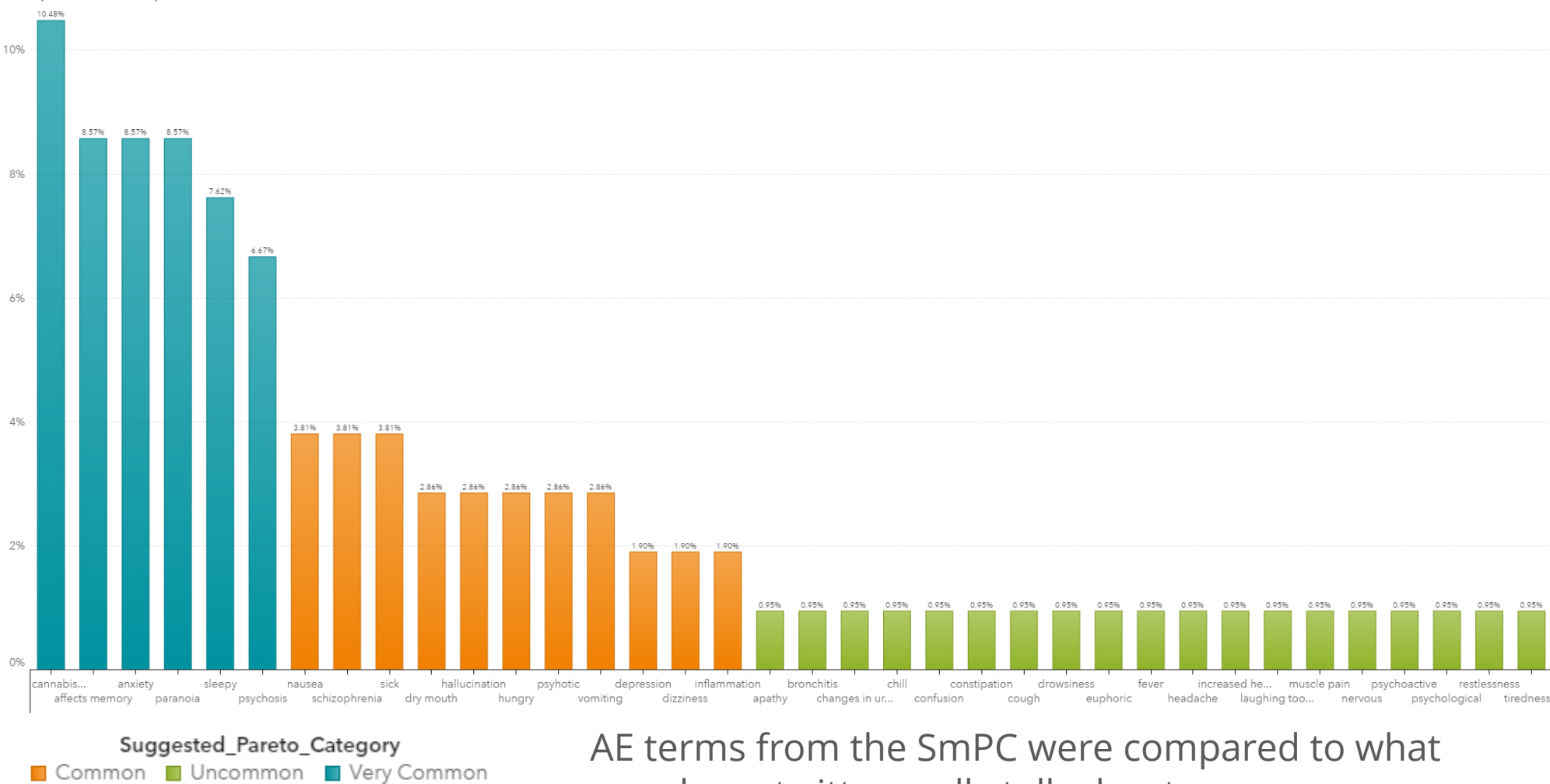
social media & patient forums



Pareto analysis for cannabis, dried flowers

Adverse Events Frequency Percentage

counts (Percent of total - Sum) 1



AE terms from the SmPC were compared to what people on twitter really talk about

diseases	Suggested_Pareto_Category	SMPC_Freq
affects memory	Very Common	NA
anxiety	Very Common	NA
apathy	Uncommon	NA
bronchitis	Uncommon	NA
cannabis withdrawal	Very Common	NA
changes in urine	Uncommon	NA
chill	Uncommon	NA
confusion	Uncommon	NA
constipation	Uncommon	NA
cough	Uncommon	NA
depression	Common	listed
dizziness	Common	listed
drowsiness	Uncommon	listed
dry mouth	Common	NA
euphoric	Uncommon	NA
fever	Uncommon	NA
hallucination	Common	NA
headache	Uncommon	NA
hungry	Common	NA
increased heart rate	Uncommon	listed
inflammation	Common	NA
laughing too loud	Uncommon	NA
muscle pain	Uncommon	NA
nausea	Common	NA
nervous	Uncommon	NA
paranoia	Very Common	NA
psychoactive	Uncommon	NA
psychological	Uncommon	NA
psychosis	Very Common	NA
psychotic	Common	listed
restlessness	Uncommon	NA
schizophrenia	Common	NA
sick	Common	NA
sleepy	Very Common	NA
tiredness	Uncommon	NA
vomiting	Common	NA

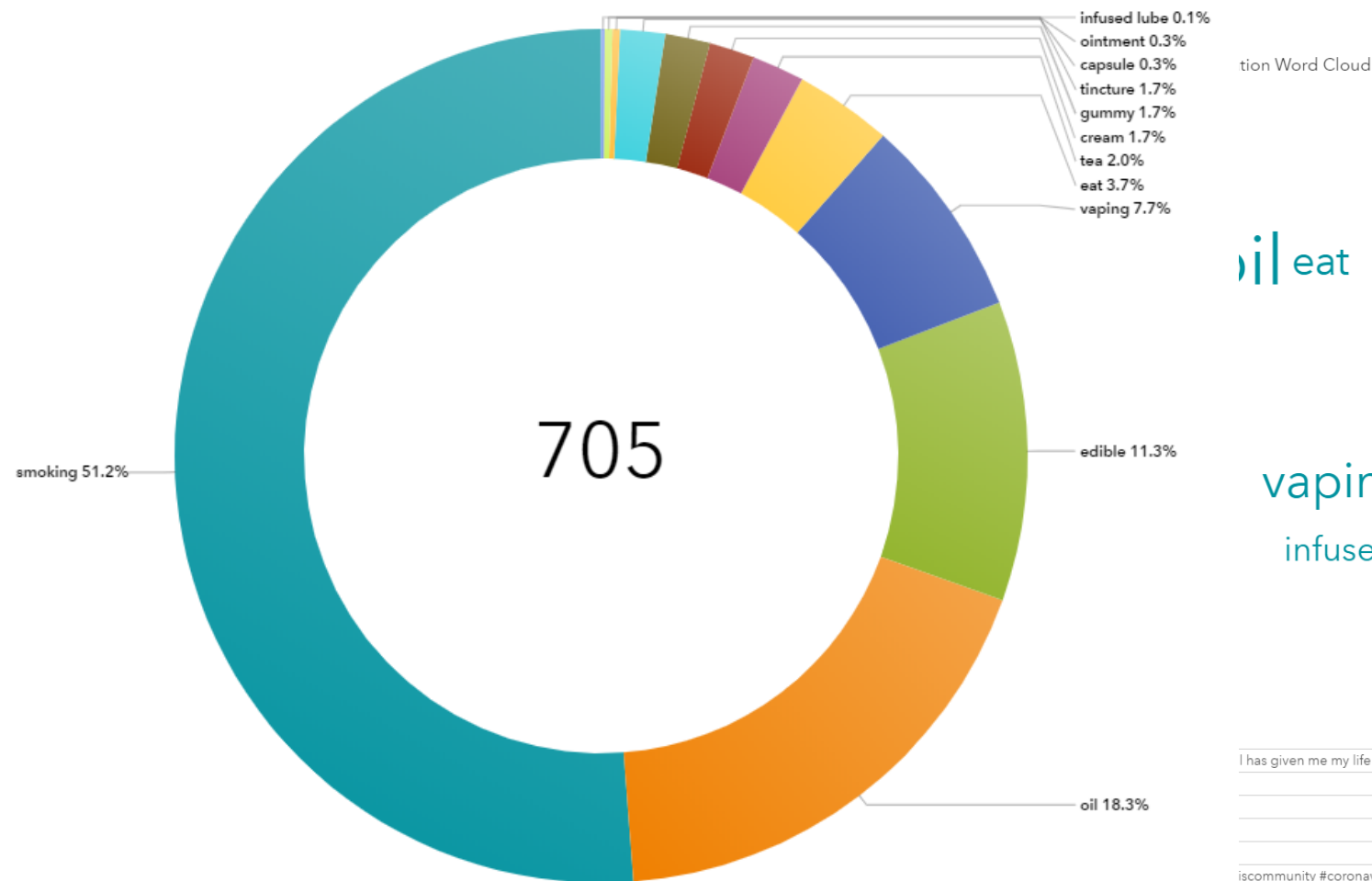
10230



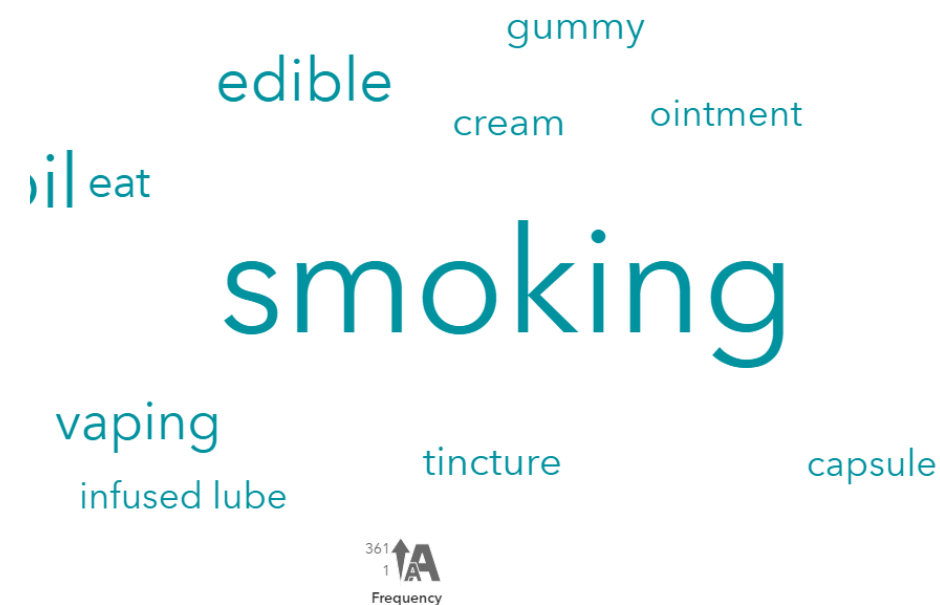
705

Frequency of Route of A

Overview dashboard for route of administration



tion Word Cloud



361
1
Frequency

Tweets for each adminis

Complete_Text

"I decided to try CBD Oil to tr
"Smoking marijuana, even ocr
"Tin pot dictators are ruling b
"Tin pot dictators are ruling b
"What were people going to c
"A number of them have redu
"Bruce Banner is a very poten
"California Democrat: 'F*ck El
"Changing your consumption
"Did you see that smoking we
"If I could live in my bong righ

_match_text_
■ smoking ■ oil ■ edible ■ vaping ■ eat ■ tea ■ cream ■ gummy ■ tincture ■ capsule ■ ointment ■ infused lube

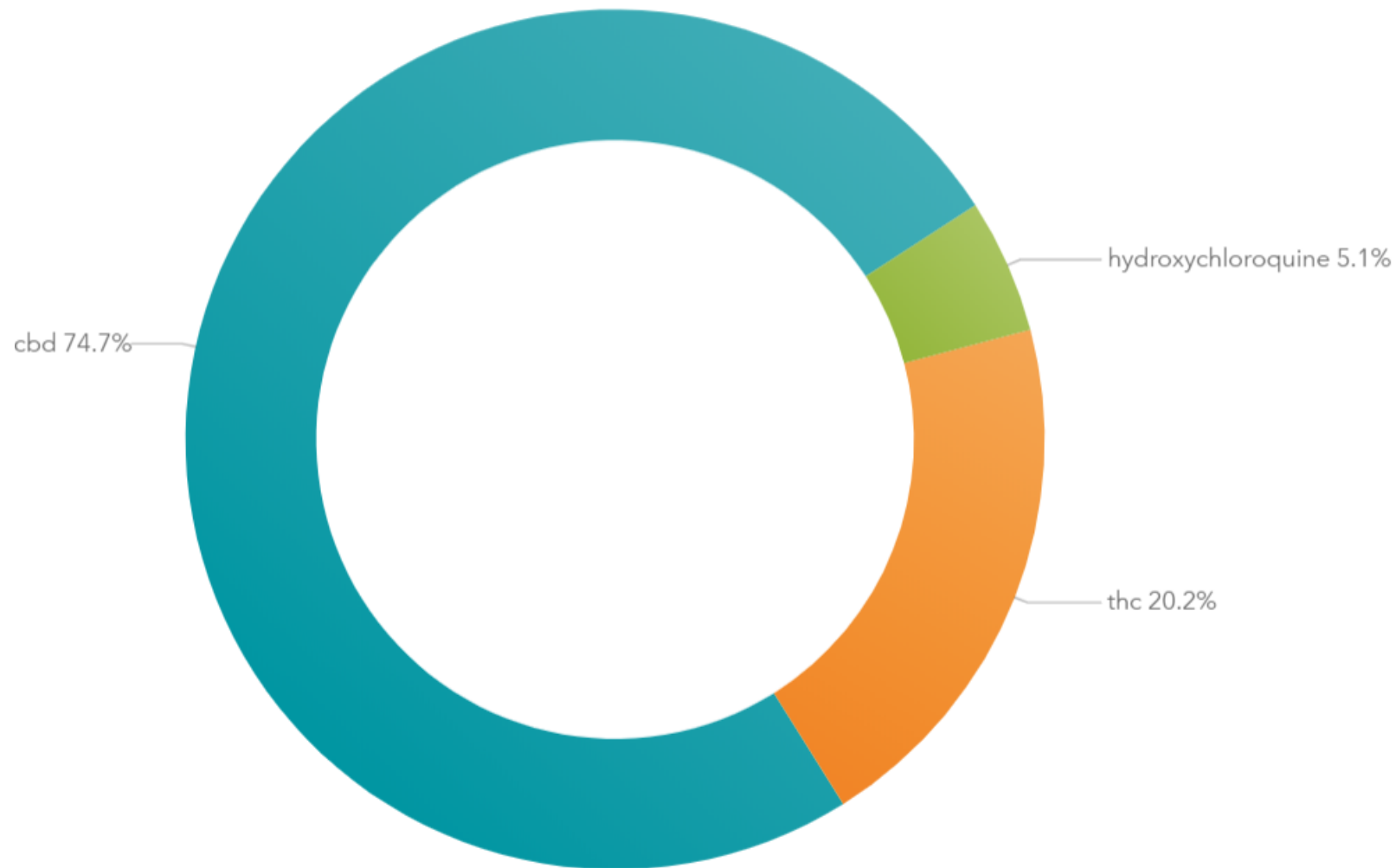
I has given me my life back!" <https://t.co/3aaEsX1MsO>

iscommunity #coronavirus <https://t.co/uSkWj7BXuG>

iplsupE

I dat virus knocking off oldies and young

Cannabis for treatment of COVID-19?



..." Australian company #IHL has developed a drug, which is a combination of **CBD / Hydroxychloroquine**, and is looking at animal trials soon with a view to fast tracking with the FDA if successful"...

A social media analysis can reveal unexpected connections

Cannabis in clinical trials for COVID-19



Exkurs: PV obligations GVP module VI

VI.B.1.1.4.

*...marketing authorisation holders should regularly screen the internet or digital media **under their management or responsibility**...*

*...If a marketing authorisation holder becomes aware of a report of suspected adverse reaction described in any **non-company sponsored** digital medium, the report **should be assessed** to determine **whether it qualifies for submission as ICSR**...*

*...the **identifiability** of the reporter refers to the possibility of verification of the **existence of a real person**...e.g. **an email address under a valid format** has been provided...*

VI.B.2.

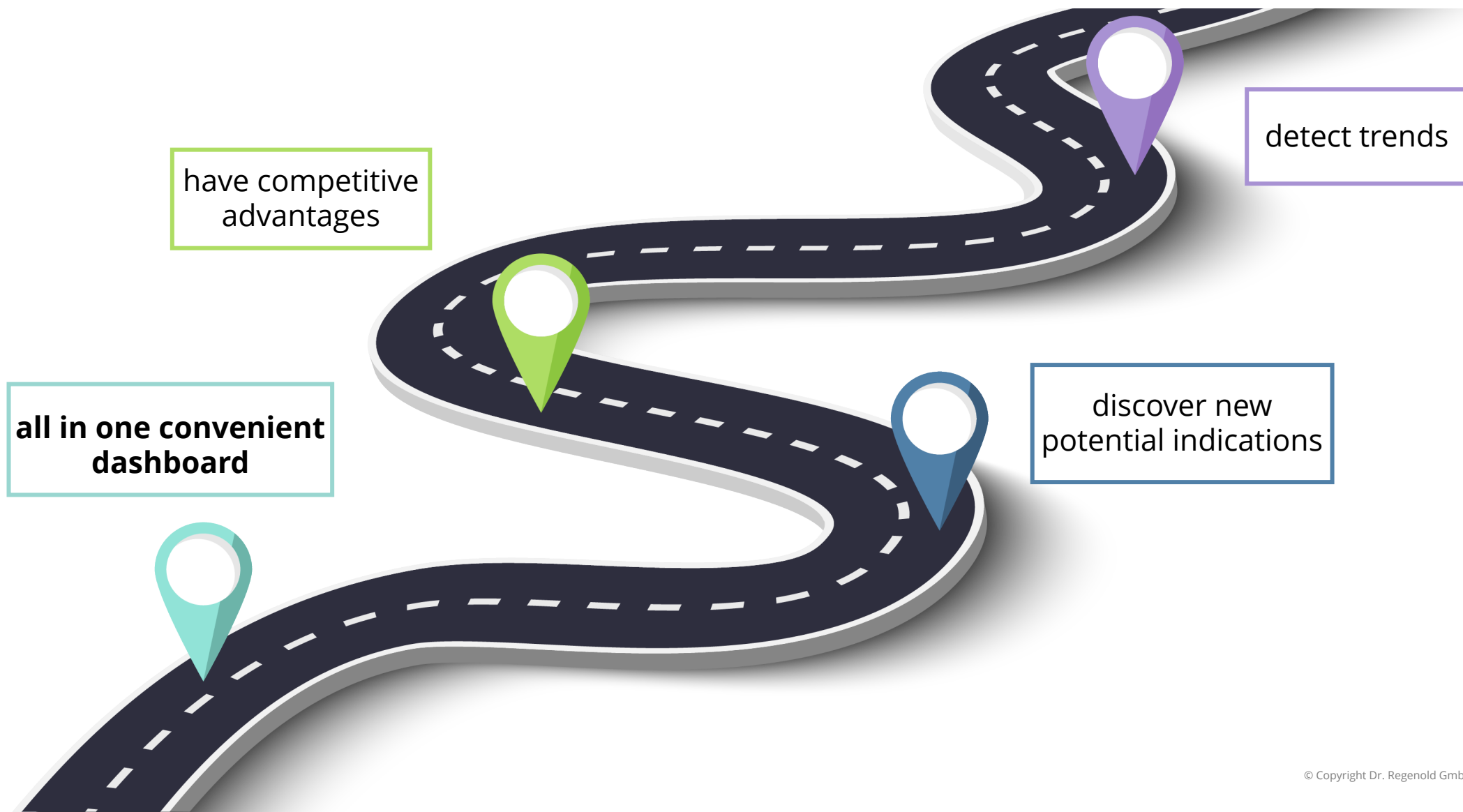
*...In addition, in accordance with **ICH E2B**, an ICSR is not valid for submission unless information concerning the qualification **and the country** is available for at least one reporter...If information on the **reporter's country is not available**, the country where the notification was received **or where the review took** place should be used in the ICSR...*

Exkurs: PV obligations GVP module VI

...one single identifiable patient...descriptors: initials, medical record number (from general practitioner, specialist, hospital, or investigation), date of birth, **age, age group,** gestation period, or **gender...**

...An ICSR should not be considered valid for submission unless information is available **for at least one of the patient qualifying descriptors...**

A roadmap to the authentic voice of the patient



Questions & Answers



Thank you.

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