

## AUTHORS

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## AFFILIATIONS

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## INTRODUCTION

Worldwide, cannabis-based medicinal products (CBMP) are becoming an increasingly popular alternative to established supportive medicinal products in cancer related symptoms including chemotherapy induced nausea and vomiting, pain, anxiety, insomnia, anorexia, in acute and palliative care.

Although there is preclinical data supporting the hypothesis of cannabinoid analgesia and further positive influence in several indications, clinical evidence is limited leading to several uncertainties. The majority of evidence based treatment guidelines especially in oncology are not considering CBMP and certified medical education is rare. In Switzerland (CH) and Germany (D) the use of CBMP is fully legalized nevertheless, reimbursement by public health insurance is restricted and therefore there is still a lack in access to CBMP for the patients.

A national survey, performed in D from 2017 to 2022, intended to generate insights on the prescription of CBMP from public insured patients only, revealed a large discrepancy between therapies with CBMP reimbursed by the health insurance and overall prescriptions in D.

The scientific patient registry Swiss Cannabis Oncology (Swiss CanOn) was developed to transform this challenging situation of CBMP by a comprehensive and integrative project, composed of the scientific digital collection of real world data (RWD) on CBMP treatment, captured by treating physicians and the patients as well as including electronic patient reported outcomes (ePROs).

## AIMS

The Swiss CanOn registry is a multicenter, bi-national, prospective, patient registry that aims to collect important and comprehensive RWD in CH and D about usage and effectiveness of CBMP, irrespective of the underlying product, as Add-On to Standard of Care (SoC) for supportive and palliative treatment of cancer related and/or chemotherapy or radiation therapy related symptoms in adult cancer patients.

The data, collected in the registry, are used as a credible new source for further scientific projects, including health service research and pharmacoeconomic analysis, to develop new necessary evidence for safe and useful prescriptions and to improve access to CBMP for patients.

In addition and to improve quality of care, CME - certified educational trainings on CBMP, are offered free of charge and online available 24/7/365 for all participating physicians, credit points are accepted in both countries, CH and D. The cooperation of all relevant stakeholders including patient organizations and scientific societies is strongly supported.

## METHODS

The first data assessment period is scheduled for two years and plans to provide at least 100 patients for first analyses. Electronic data capture and patient reported outcomes including mobile health (mHealth) technologies are used in this project to optimize data collection, diminish missing data and to better control the data collection workflow.

At patient's registry inclusion, participating physicians collect data such as diagnosis, former medical treatment, and information on CBMP prescription like extract, flowers, Dronabinol or finished medicinal products in off-label use with specific information concerning CBD:THC ratio, concentration, and initial dosage. Patients download the corresponding patient Smartphone App and continuously enter information on e.g. CBMP dosage, symptoms, well-being, cognition, vital signs and concomitant medication.

The availability of the RWD set will enable descriptive and exploratory analyses in order to gain insight about

- (1) frequency of cancer types treated with CBMP,
- (2) underlying indication for CBMP prescription,
- (3) the prescription of CBMP like e.g. product types, application form, CBD:THC ratio, and concentration,
- (4) information on effective dose titration,
- (5) changes of symptomatology, well-being, and cognition over time
- (6) effects of medicinal cannabis treatment on concomitant medication use
- (7) potential moderating effects of demographics and baseline disease characteristics on treatment effectiveness and biological parameters.
- (8) duration of treatment
- (9) if applicable, reasons for therapy withdrawals

Although the generated data set will be heterogeneous due to the nature of patient registry, this registry seeks to investigate first trends concerning the use of medical CBD:THC cannabis products in real-world conditions.

## RESULTS

The registry has been approved by Ethics in Zuerich and initiated in CH, 6 patients have been included, so far. Further, vote of Ethics in Mainz, D has been obtained and the first German site has recently been initiated. Recruitment of further sites is in progress.

The following represents a first and purely descriptive exemplary display of results.

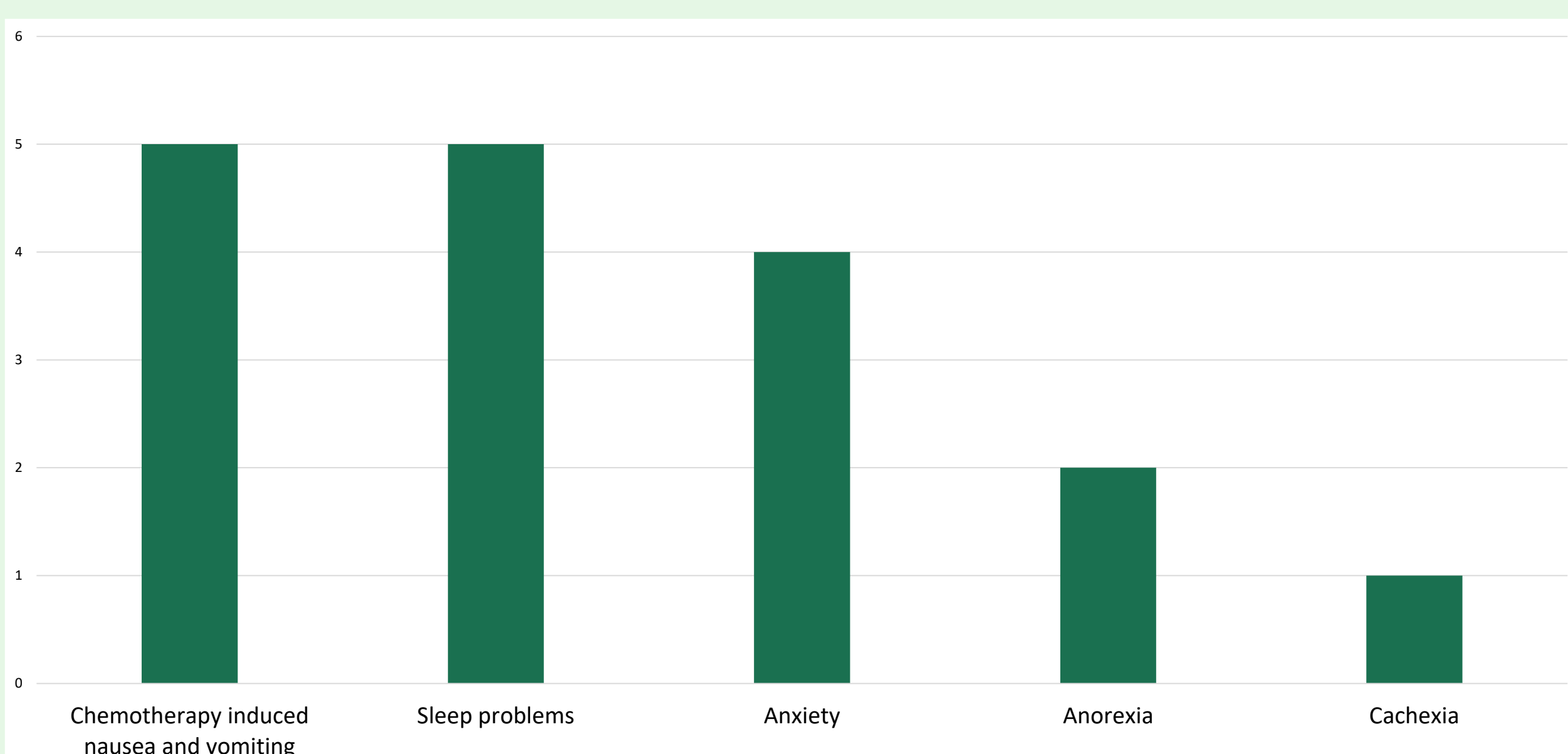


Figure 1: Medical indication for prescription of cannabis-based medicinal products

A first descriptive analysis shows that the most frequently mentioned medical indications for prescription of CBMP were Chemotherapy induced nausea and vomiting (CINV) and sleep disturbance, followed by anxiety, anorexia and cachexia (Figure 1). For the first 6 patients, pain was not among the indications for prescribing medical cannabis. When specifying the indication, the physicians were allowed to give multiple answers.

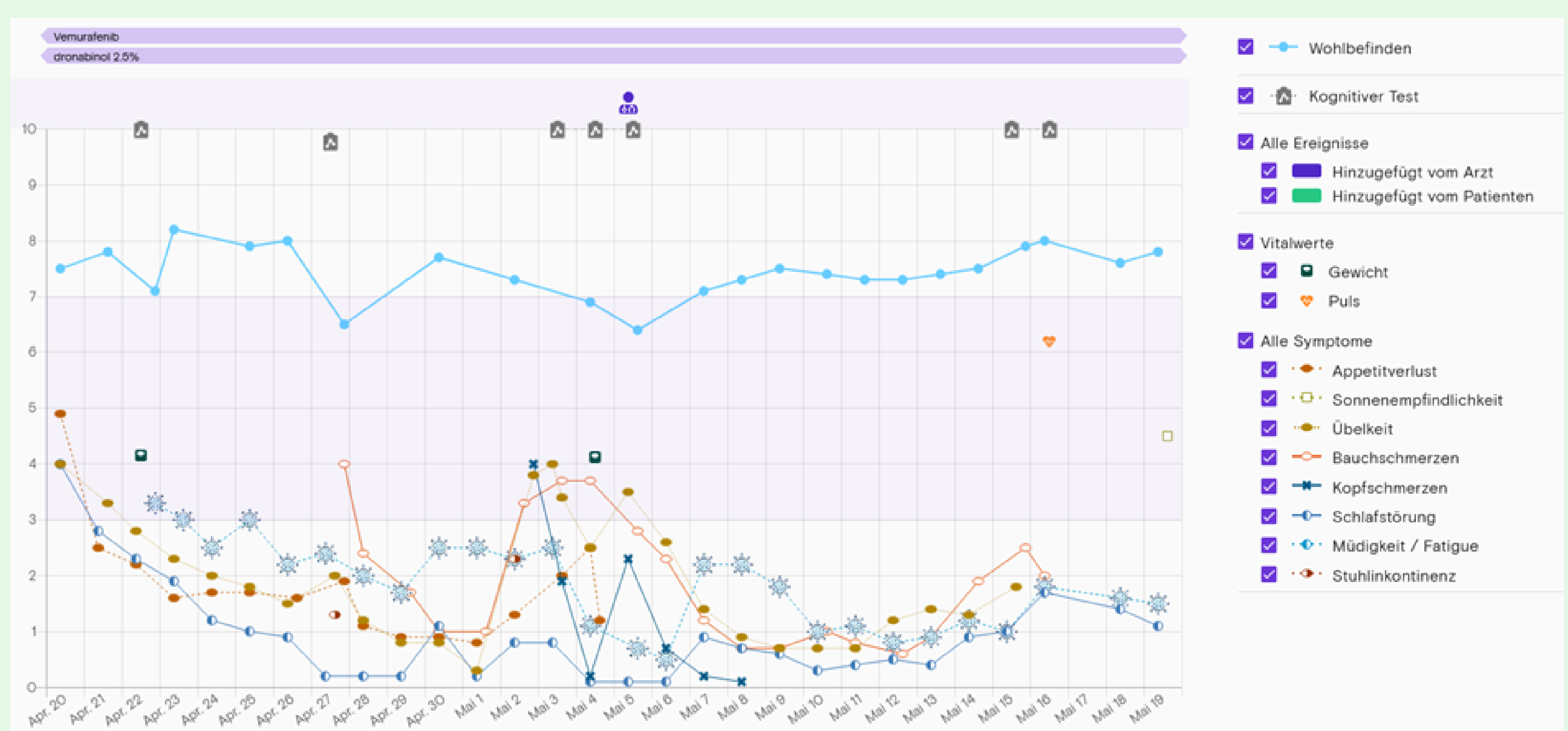


Figure 2: Example export of the electronic patient reported outcomes (only available in German language)

Figure 2 shows an example data export of an already included patient of the Swiss CanOn registry and provides an insight on information obtained through the collection of ePRO data. As the export shows a close monitoring of various symptoms and their severity is possible from the beginning of the prescription of CBMP.

Data showed that 50%, i.e. 3 patients stopped registry participation early, whereby 2 of these premature discontinuations were requested by the patient and one was instructed by the physician. Reasons were either side effects or preference for non-medicinal cannabis.

So far, this is the only descriptive data presentation that is available at this point of time. A further analysis of the 6 patients already included in CH would not be meaningful.

The CME certified medical education on CBMP offered for all physicians are widely accepted. To date 3 CME webinars were performed with increasing number of participating medical doctors (>300 participants at the live events). A next webinar is currently under development. Further, the registry website, listed at the swiss website for medical registries (FMH), is used as a platform to inform all interested parties including patients, medical doctors, supporting medical cannabis industry and further financial investors

For improving reimbursement of CBMP for the participating patients, the dialogue with public health insurance already started.

## CONCLUSIONS

Despite the limited available data at the current point, the presented methods and data show that the SwissCanOn registry is an adequate method to (1) collect a sustainable data basis for a variety of different research questions, (2) serve as a solid basis leading to further clinical investigations, (3) create a growing network of patients, academic and industrial partners emphasizing science, (4) allow physicians to track efficacy and side effects of CBMP therapy with their patients, and (5) associate the project with an academic educational program on medicinal cannabis. By collecting data from all oncological patients, treated with CBMP in CH and D, the data basis of the Swiss CanOn registry is to be steadily increased until the end of the first period late 2023.

**KEY WORDS:** medicinal cannabis, oncology, scientific patient registry, real-world data

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www.swisscanonregistry.com

