

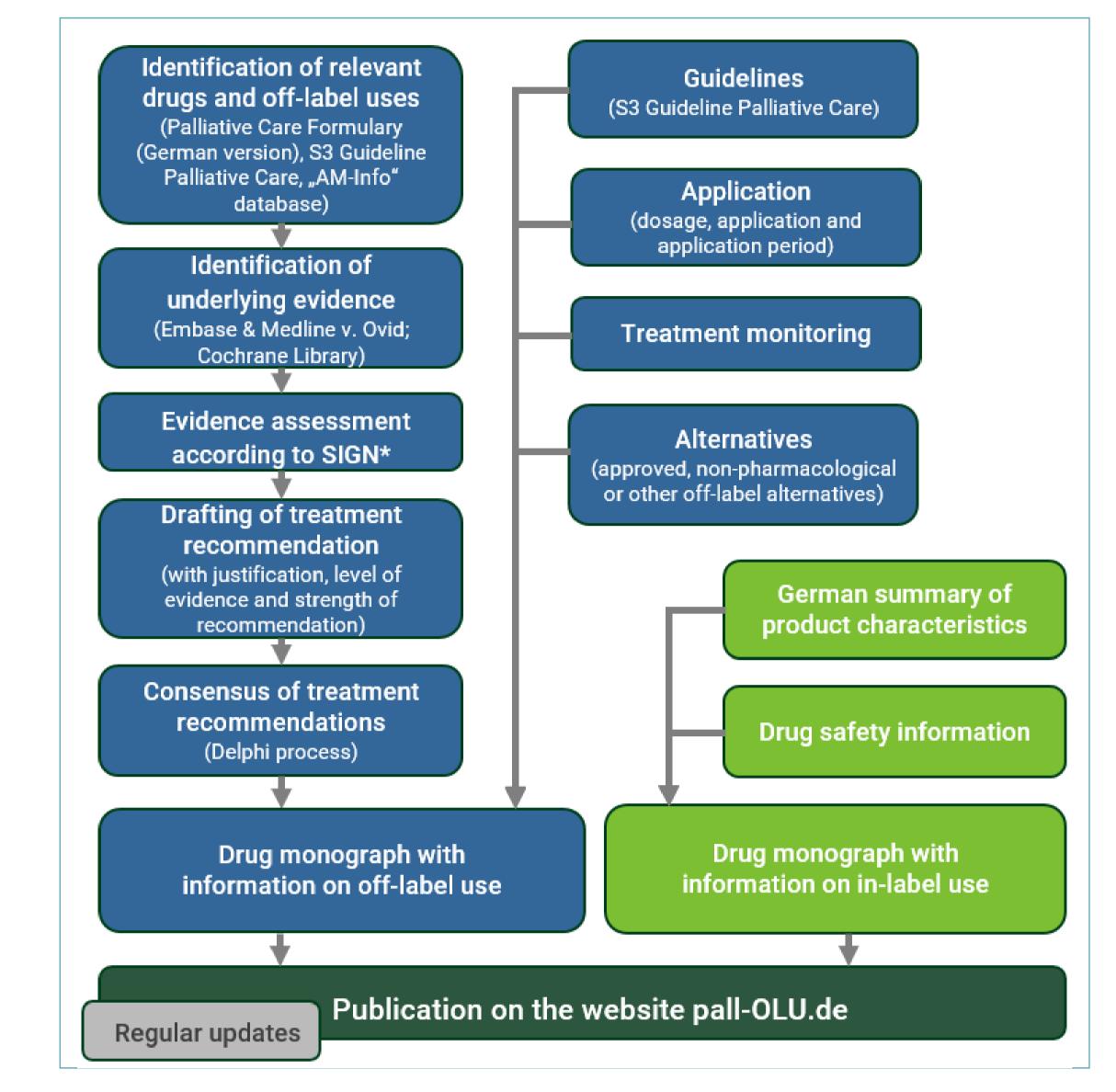
Klinik und Poliklinik für Palliativmedizin

# PALL-OLU.DE: A NEW DATABASE ON THE OFF-LABEL USE OF DRUGS IN PALLIATIVE MEDICINE

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#### **Background and importance**

The main focus of palliative care is the relief of distressing symptoms. Off-label drug use (OLU, off-label use) has become an integral part of daily practice. Up to 50% of drugs are used off-label; yet there is limited support for these uses in official recommendations such as guidelines. In addition to liability and reimbursement issues, the efficient search for evidence-based information for treatment planning is of particular importance.<sup>2</sup> However, in everyday clinical practice, health care professionals often lack the time and resources for such research.



## Aim and objectives

The database pall-OLU.de is designed to provide healthcare professionals with quick and easy access to evidence-based treatment recommendations for OLU in palliative care free of charge.

#### Materials and methods

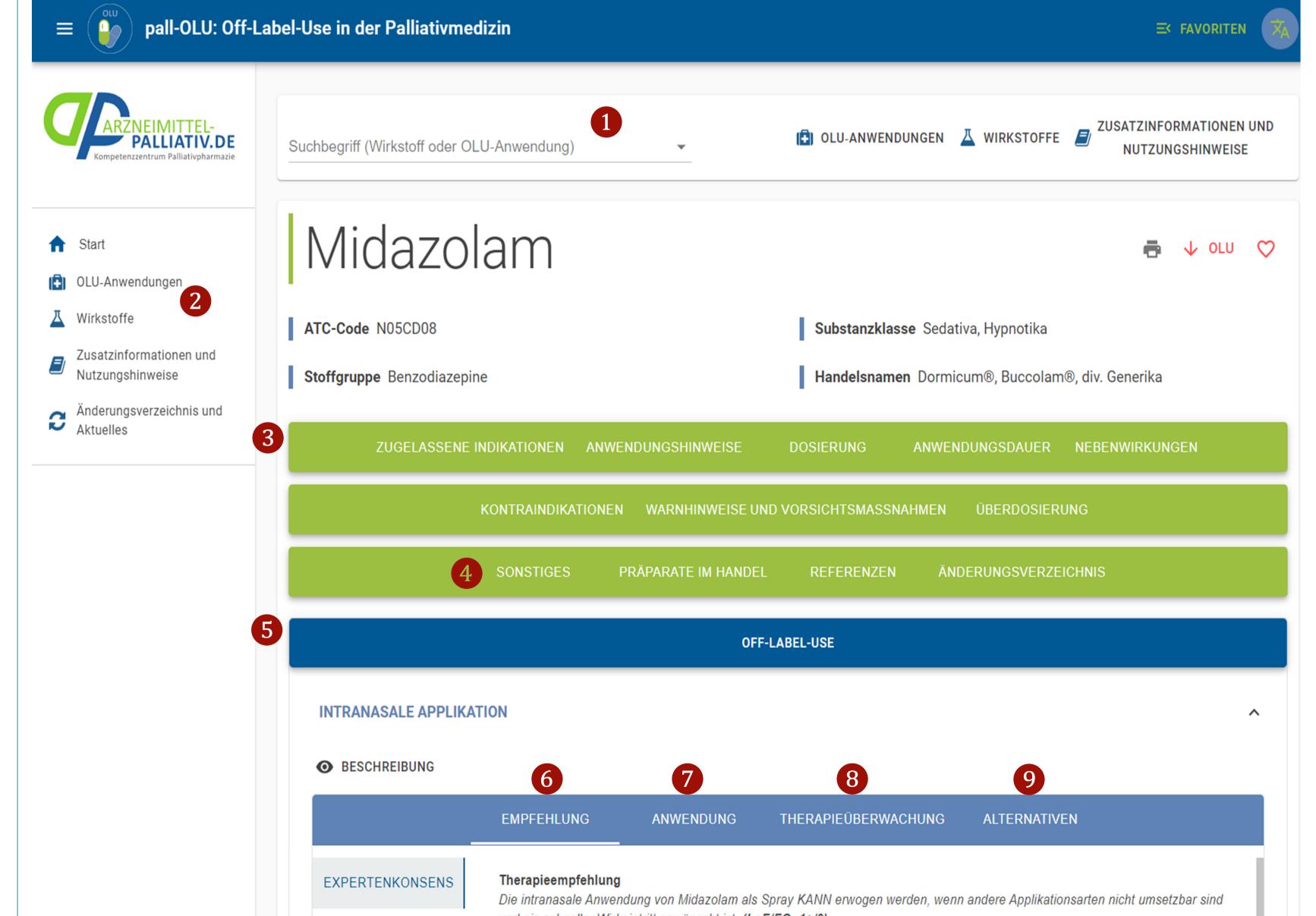
Relevant drugs and their OLU in palliative care are identified using a systematic approach. Treatment recommendations are subsequently developed based on the best available evidence and agreed in a web-based, two-round Delphi process with international palliative care experts.<sup>3</sup> The consented off-label treatment recommendations are eventually presented in drug monographs and include additional information, e.g. on monitoring or alternative pharmacological and nonpharmacological treatment options (Fig. 1).

## Results

The first 38 treatment recommendations were agreed upon in 2022. Seventy experts participated in each round (response rate: 1<sup>st</sup> round 72,9% / 2<sup>nd</sup> round 67,9%). Since

**Fig.1:** Systematic process of developing treatment recommendations for off-label drug use in palliative care und additional drug information, \*SIGN: Scottish Intercollegiate Guidelines Network

2023 recommendations are accessible free of charge on the website pall-olu.de. In the meantime, further 46 treatment recommendations from the second and third Delphi processes are also available in the database. Figure 2 shows an example of a monograph from the database.



Search options:

**1** by search term: Off-label-Use ("OLU Anwendung") indication or route of administration or active ingredient ("Wirkstoff") 2 all available monographs are listed under OLU applications ("OLU Anwendungen") or active ingredients ("Wirkstoffe")

## Drug monograph ILU (in-label use):

**3** structured presentation ILU based on the German summary of product characteristics

## 4 OTHER

further relevant information about the active ingredient (e.g. safety alerts or compounded drugs)

Drug monograph OLU (off-label use):

**5** OFF-LABEL-USE structured presentation of

information on OLU

6 RECOMMENDATION consented treatment

recommendations (expert consensus) or palliative care guideline<sup>2</sup> recommendations 7 ADMINISTRATION

information on dosage, administration and duration of therapy

**8** TREATMENT MONITORING

important information for assessing treatment effectiveness and tolerability

9 ALTERNATIVES

references to approved, nonpharmacological or other offlabel alternatives



#### **Fig.2:** Screenshot of the midazolam monograph from pall-OLU.de database

#### **Conclusion and relevance**

pall-OLU.de provides a quick and easy access to evidence-based information. The database fills an information gap and makes an important contribution to safe and effective pharmacotherapy in palliative care. In total, the aim is to publish around 400 treatment recommendations for around 80 drugs. A smartphone app is under development.

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#### References

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