

# Real-World Data Sources for Oncology in 5 major European Countries: A Targeted Literature Review

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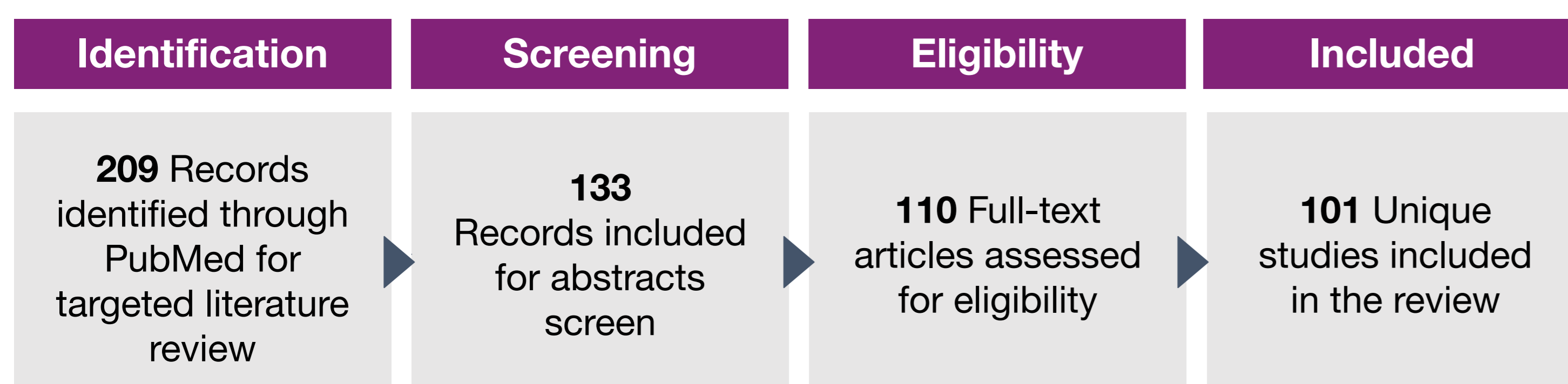
## Background

- With recent updates to the guidance for leveraging real-world evidence (RWE), it is expected to play an increasing role in Health Technology Assessment (HTA) submissions in Europe<sup>1,2</sup>
- To our knowledge, there are no peer-reviewed publications that summarize the current landscape of real-world data (RWD) in Europe
- Using a targeted literature review, we evaluated the use of RWD to support oncology studies in France, Germany, Italy, Spain, and the United Kingdom (UK) (the EU5)

## Methods

- The search strategy included terms for RWD (e.g., “real?world data”, “electronic health record”) related to “oncology” or “cancer” and the EU5. The results were limited to publications during 2019-2024 and the “Observational Study” article type
- The query was conducted in PubMed. The results were screened sequentially by title, abstract, and full text to ensure each article met the selection criteria

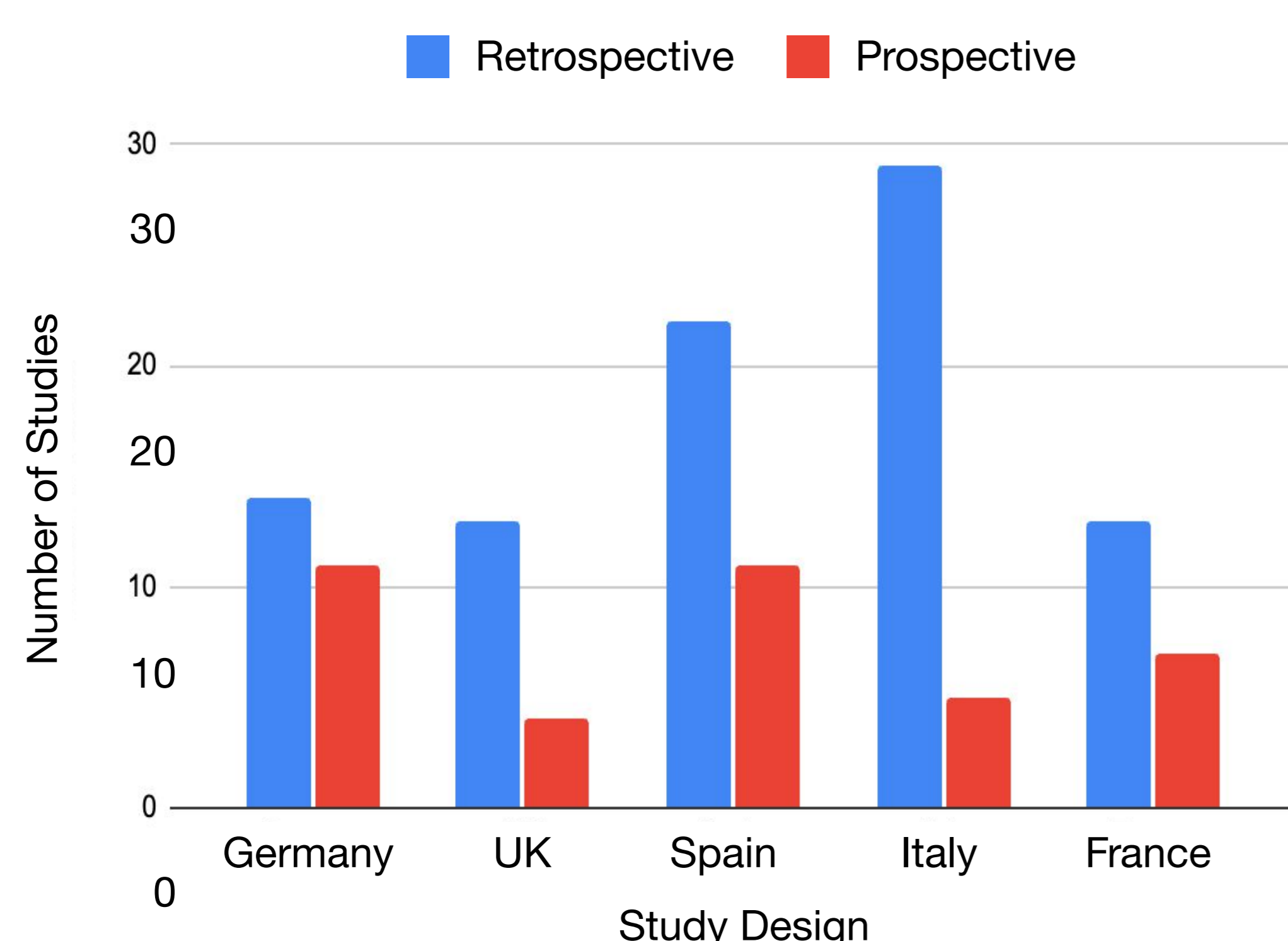
Figure 1: PRISMA Diagram



## Results

- A total of 101 publications met the eligibility criteria. The number of publications meeting the search criteria, by country, were as follows: France (20), Germany (25), Italy (33), Spain (34), and the UK (17). Many (65%) studies included multiple sites, with 16% spanning more than one country
- Prospective observational studies were most common in Germany (44%) and France (35%), while retrospective chart review was most common in the UK (47%), Spain (38%), and Italy (47%)

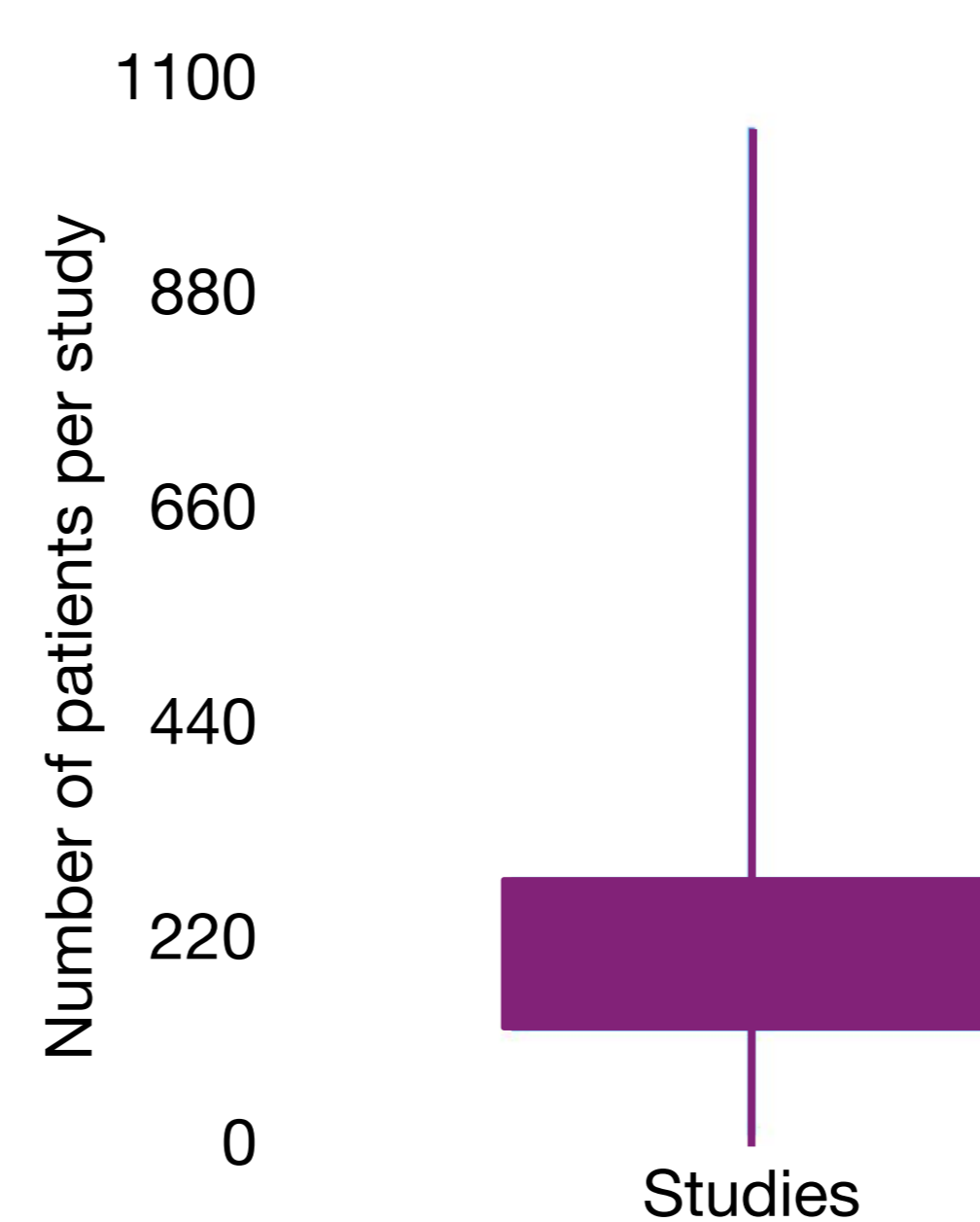
Figure 2: Study Type by Country



## Results (continued)

- Standard or syndicated RWD was generally not used: 91 out of 101 studies appear to rely on RWD that was generated or curated specifically for the objectives reported by the publication
  - Specific databases were named in 52 (51%) of the studies. Most named databases appeared only once, but 5 (ESME, InGef, Network Oncology, RENAPE, TLN) were used across 2 studies

Figure 3: Distribution of Sample Size



- Among the studies included in the review, 98 reported the total number of patients included. The number of patients per study varied widely: median = 276 interquartile range [123, 1,057]

Abbreviations: ESME, Epidemiological Strategy and Medical Economics; RENAPE, National Network for the Treatment of Rare Peritoneal Malignancies; TLN, Tumour Registry Lymphatic Neoplasms.

## Conclusion

Recently published RWD sources for oncology in the EU5 were primarily limited to studies designed for a specific purpose, rather than more general data resources that can support a variety of objectives.

## Future Directions

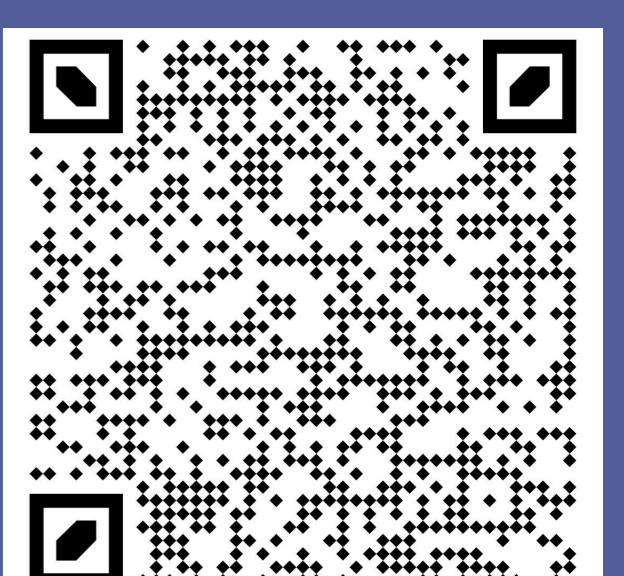
- Curating RWD is a resource-intensive task. However, many RWD sources are only used in 1 or 2 research studies. The curation of standardized oncology RWD sources that can support a variety of objectives has potential to improve efficiency in the advancement of research in oncology
- Similar reviews can be expanded to other regions, such as Asia, to provide a broader summary of the RWD landscape
- Additional manual review of regulatory and HTA submissions to identify other RW sources will be beneficial in better understanding how RWD have been used in the EU5 space

## References

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2. European Medicines Agency. High-quality data to empower data-driven medicines regulation in the European Union. [www.ema.europa.eu/en/news/high-quality-data-empower-data-driven-medicines-regulation-european-union](https://www.ema.europa.eu/en/news/high-quality-data-empower-data-driven-medicines-regulation-european-union) (2023).

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