# The potential of using Nordic real-world evidence to support PICO assessment of a hypothetical oncology drug and hip replacement medical device

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## Abstract

The Nordic registries are well known for conducting longitudinal and extensive studies, where a personal identification (ID) number links data from several registries for an individual-level multi-variable approach. The objective of this assessment was to explore how Nordic registries can support a PICO (population, intervention, comparator, outcome) assessment/simulation by providing real-world data.

## Background

- The implementation of European Union (EU) Joint Clinical Assessments has elevated the importance of exploring PICOs, where access to extensive health data will be essential.
- Nordic health data registries are often referred to as goldmines because they are[1]:
  - ✓ Extensive (**Figures 1 and 2**) and of high quality
  - ✓ Longitudinal
  - ✓ Able to link using unique personal IDs

## Objective

To assess how Nordic real-world evidence (RWE) can be utilized in a PICO assessment and explore what registries could be relevant for a hypothetical oncology drug and hip replacement medical device product.

## Conclusions

- Nordic RWE contributes with valuable insights to every PICO dimension of a hypothetical oncology drug and medical device.
- The RWE strategy depends largely on the type of product and therapeutic area.
- The Nordics is a valuable region in terms of RWE, even where the Nordics is not the intended market, due to high-quality registries and personal identity numbers allowing for linkage of data sources.
- With relevant data sources and established expertise, PICOs can be updated continually with minimal effort, ensuring continued relevance and alignment with evolving evidence.

## References

**1.** Joint Nordic Registers and Biobanks – A goldmine for health and welfare research. NordForsk. Published 2025. Accessed September 22, 2025. https://www.nordforsk.org/2014/joint-nordic-registers-and-biobanks-goldmine-health-and-welfare-research **2.** Registerforskning och hälsodata. Dataguiden.se. Published March 20, 2025. Accessed September 26, 2025. https://dataguiden.se/planera-och-identifiera/olika-datakallor **3.** Helsedata.no. Accessed September 26, 2025. https://helsedata.no/en/data-sources/?page=1&sort=0 **4.** Venkatraman V, Mani P, Ussing A. Mapping the healthcare data landscape in Denmark. Danish Life Science Cluster. August 2015. Accessed September 26, 2025. Mapping-the-Healthcare-Data-Landscape-in-Denmark-for-web.pdf **5.** National Health Registers. Sundhedsdatastyrelsen.dk. Accessed September 26, 2025. https://english.sundhedsdatastyrelsen.dk/health-data-and-registers/national-health-registers **6.** Kliniske kvalitetsdatabaser. Sundhedsdatastyrelsen.dk. Accessed September 26, 2025. https://sundhedsdatastyrelsen.dk/data-og-registre/kliniske-kvalitetsdatabaser **7.** FinnGen. Register data. Published 2023. Accessed September 26, 2025. https://www.finngen.fi/en/register-data **8.** THL. Register descriptions. Published September 23, 2024. Accessed September 26, 2025. https://thl.fi/en/statistics-and-data/data-and-services/register-descriptions

## Methods

A review of RWE sources which could support a PICO assessment for a hypothetical oncology drug (Cenpicomab) and hip replacement medical device (Cenpicohip) was explored, where relevant registries in each of the Nordic countries (Denmark, Finland, Iceland, Norway, Sweden) were sought for addressing each PICO dimension.[2-5]

**Figure 1. Nordic health data registries by country**

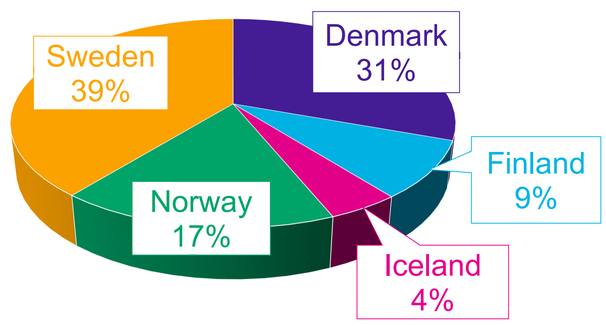
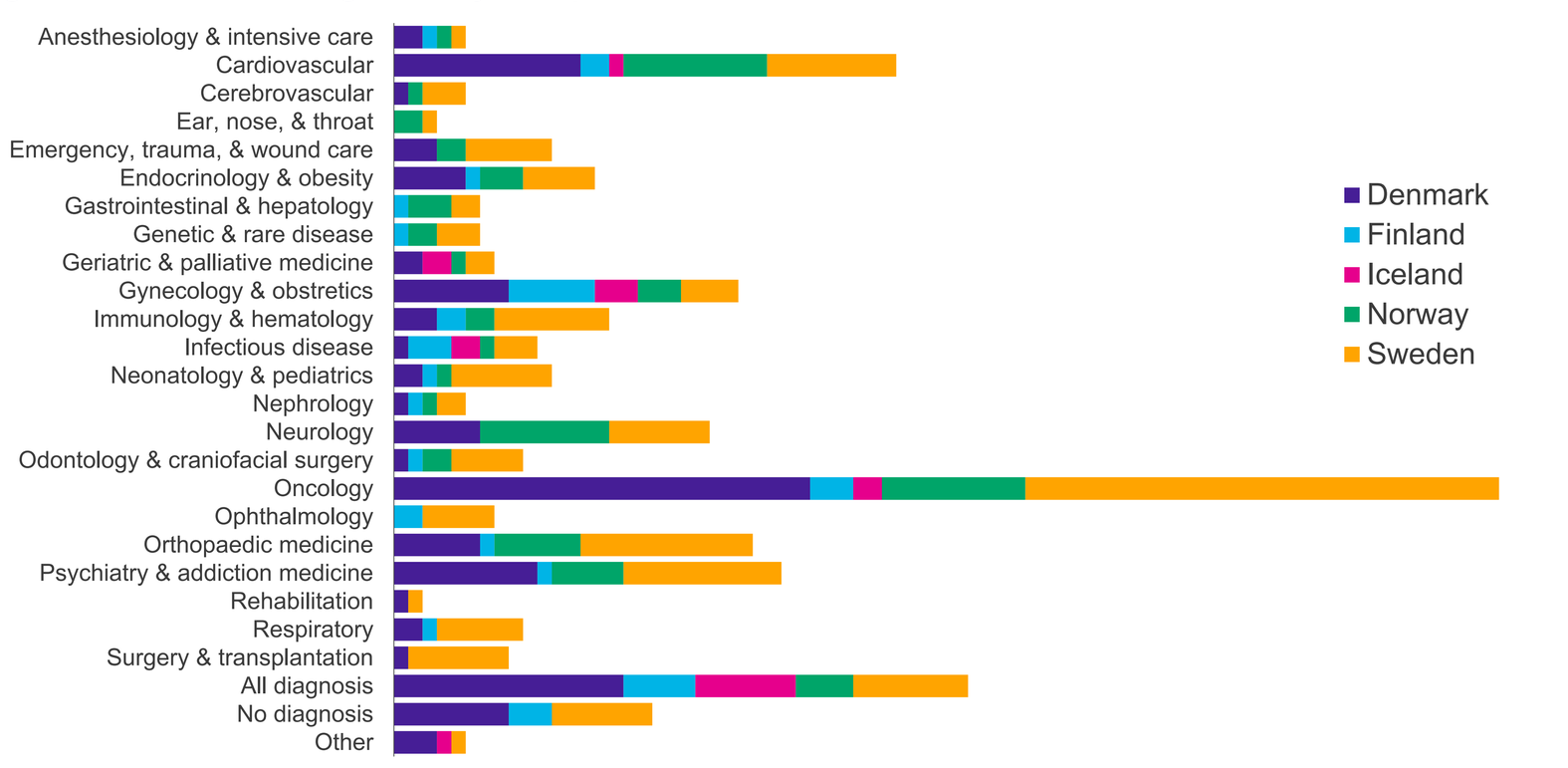



**Figure 2. Nordic health registries by therapeutic area**




## Results

**Table 1. Outline of Nordic health data registries to support different dimensions of PICOs for the hypothetical drug Cenpicomab and medical device product Cenpicohip**

| PICO | Generic project | Drug oncology (Cenpicomab) | Medical device hip replacement (Cenpicohip) |
|---|---|---|---|
| **(P)opulation** | Clinical context<br>• Epidemiology<br>• Clinical management<br>• Drug utilization<br>• Comorbidities<br><br>**Registries:** NPR, PDR, CR | NPR (D, F, I, N, S)<br>PDR (D, F, I, N, S)<br>CaR (D, F, I, N, S)<br>Lung cancer CR (D,N,S)<br>Palliative care CR (D, S)<br>Pathology registry (D) | NPR (D, F, I, N, S)<br>Hip arthroplasty CR (D,N,S)<br>Medical implant registry (D) |
| **(I)ntervention** | Post-launch follow-up<br>• Investigate associations and impact<br>• Safety studies<br>• Effectiveness<br><br>**Registries:** NPR, CR, PDR | PDR (D, F, I, N, S)<br>Lung cancer CR (D,N,S) | NPR (D, F, I, N, S)<br>Hip arthroplasty CR (D,N,S)<br>Medical implant registry (D) |
| **(C)omparator** | Clinical context<br>• Epidemiology<br>• Clinical Management<br>• Drug utilization<br><br>**Registries:** NPR, PDR, CR | PDR (D, F, I, N, S)<br>Lung cancer CR (D,N,S) | NPR (D, F, I, N, S)<br>Hip arthroplasty CR (D,N,S)<br>Medical implant registry (D) |
| **(O)utcome** | Support the planning and validity of studies<br>• Design<br>• Safety/Effectiveness<br>• Feasibility<br>• Representativeness<br>• Validity<br><br>**Registries:** NPR, CR | NPR (D, F, I, N, S)<br>PDR (D, F, I, N, S)<br>CaR (D, F, I, N, S)<br>Lung cancer CR (D,N,S)<br>COD (D, F, I, N, S)<br>Palliative care CR (D, S)<br>Pathology registry (D) | NPR (D, F, I, N, S)<br>PDR (D, F, I, N, S)<br>Hip Arthroplasty CR (D,N,S)<br>Medical implant registry (D) |

CaR – cancer registry; COD – cause of death registry; CR – clinical registry; D – Denmark; F – Finland; I – Iceland; N – Norway; NPR – national patient registry; PDR – prescribed drug registry; S – Sweden.

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Presented at: ISPOR Europe 2025
9-12 November 2025 | Glasgow, Scotland, UK
Funded by Cencora.