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## Background and Objective

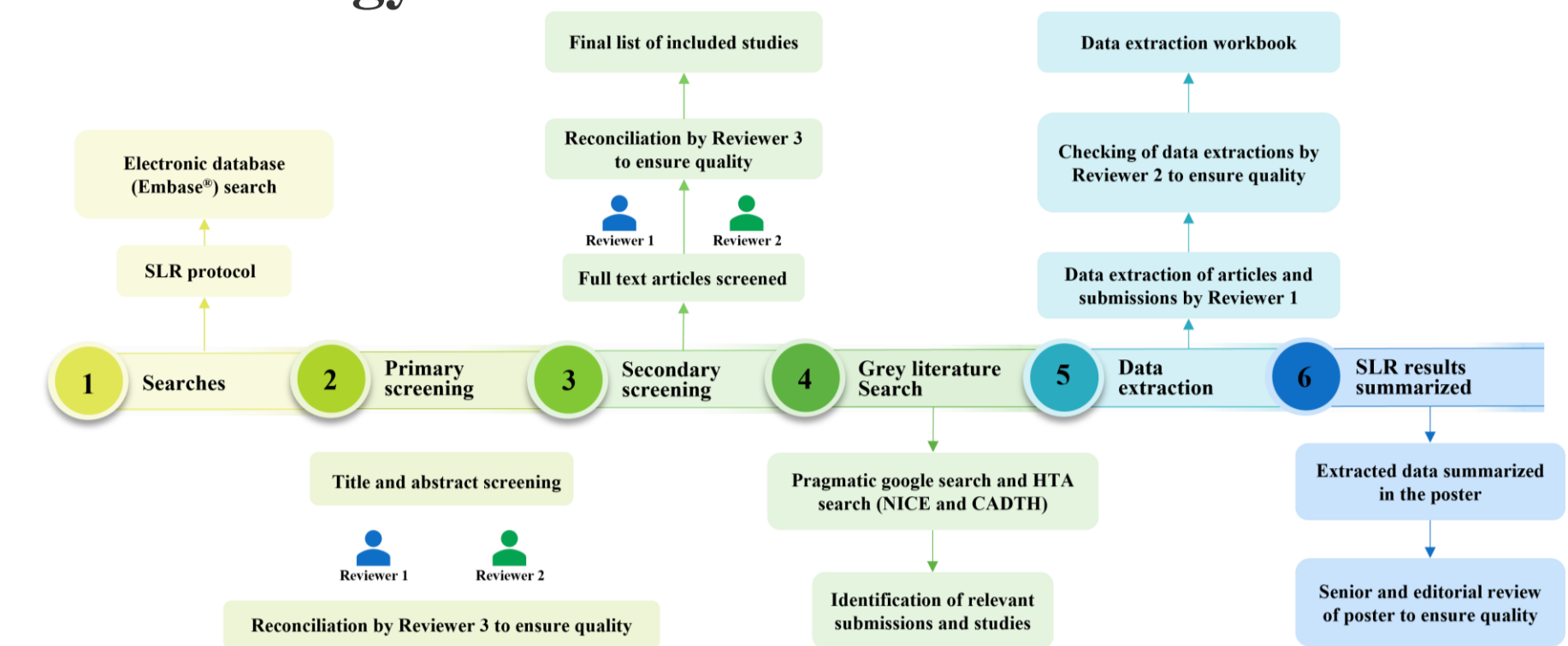
### Background:

- Nordic real-world data (RWD) offers unique and globally unparalleled opportunities in health registry-based research. It provides virtually complete follow-up and exact censoring information on lives and health of all citizens
- Key features of Nordic RWD include administrative claims-type data with complete population of 27.5 million<sup>1</sup>, with holistic information about patients including diagnoses, prescriptions, mortality, PROs, severity, genetics, costs, and more with a long follow-up of 20+ years, and patient level data with deterministic linkages<sup>2,3</sup>
- Similarities in data structure and variables enable the combination of data and execution of parallel studies across the Nordics<sup>3</sup>
- Ability of Nordic RWD to inform HTA in non-Nordic settings may enable faster patient access to treatments

**Objective:** Systematically review published literature and HTA submissions to identify the usage of Nordic RWD to support HTA in non-Nordic settings.

## Methodology

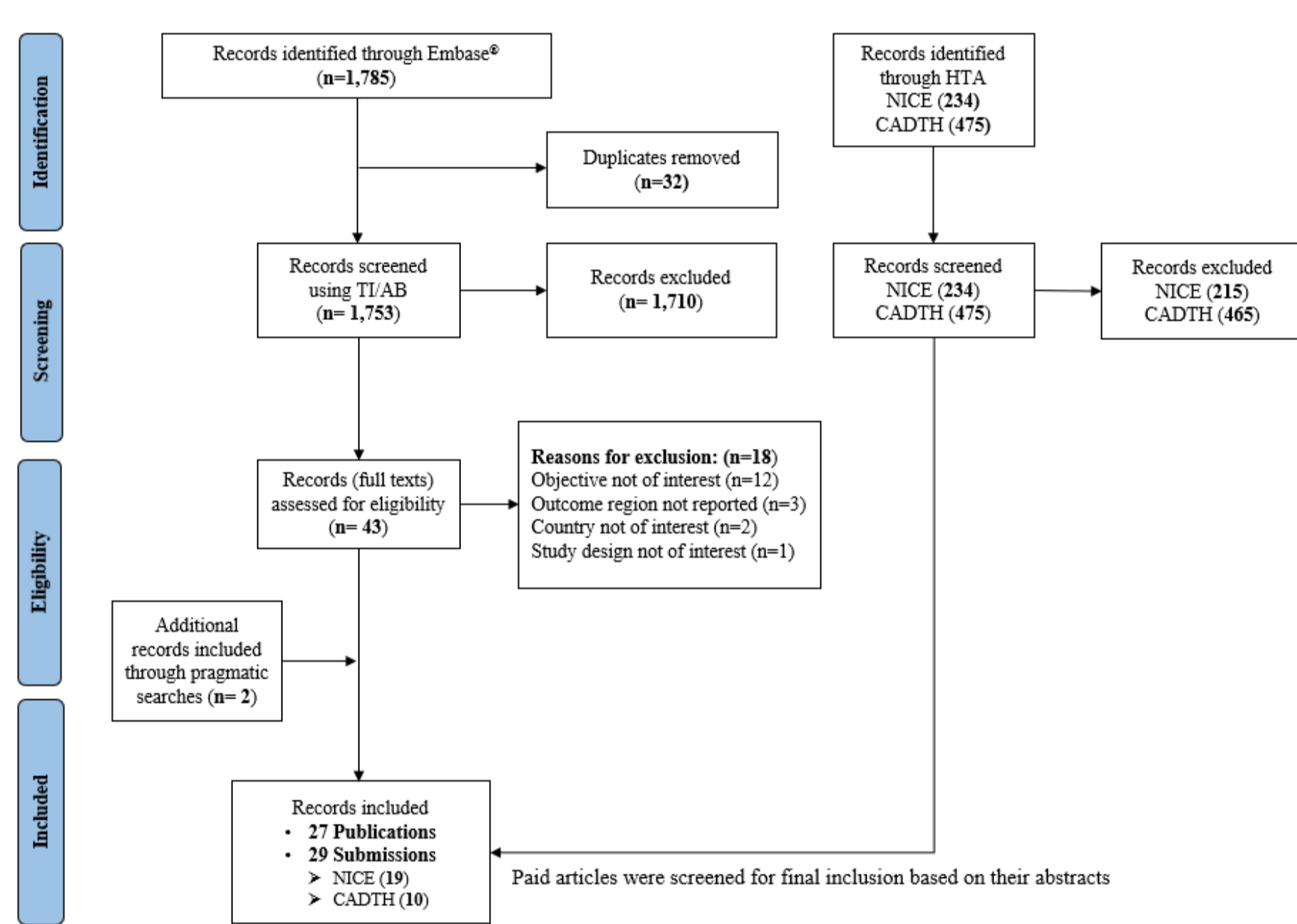
Figure 1: SLR methodology



- Literature searches in Embase<sup>®</sup> (from inception of database in 1974), Google searches, and screening of HTA submissions to NICE and CADTH (January-2021 and onwards) were conducted in June 2023
- Utilization of Nordic RWD in HTA submissions, and actual or suggestive utilization of Nordic RWD in the English language publications led to inclusion

## Results

Figure 2: PRISMA diagram



- A total of 1785 records from Embase<sup>®</sup>, and 234/475 submissions from NICE/CADTH databases were retrieved
- For publications
  - After removing duplicates, 1753 records were reviewed for TI/AB screening which led to inclusion of 43 records
  - Full text screening led to inclusion of 25 records.
  - Finally, a total of 27 records (25 from Embase<sup>®</sup> and two from additional pragmatic searches) were included
- For HTA submissions, screening led to inclusion of 29 submissions (19/10: NICE/CADTH) (Figure 2)

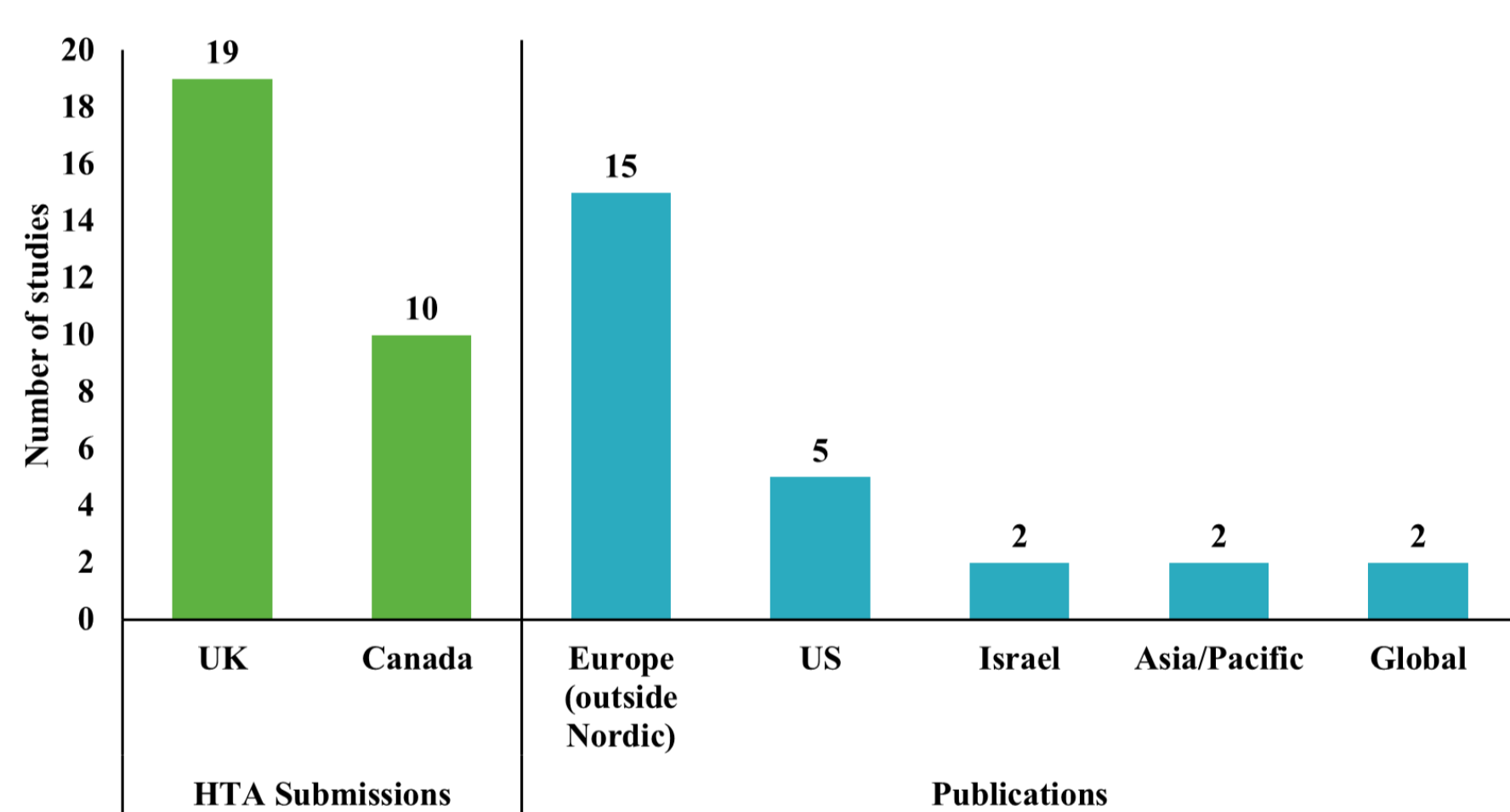
Figure 3: RWD source geography<sup>#</sup>

Source Country	Sweden	Denmark	Norway	Finland	Iceland	Nordic
HTA Submissions (n: 29)	22	6	5	3	0	1
Publications (n: 27)	16	13	5	5	1	3

<sup>#</sup>Some records reported data from >1 source country

- Most records reported utilization of Swedish RWD (75.8% HTA; 59.3% publications), followed by Danish RWD (20.7% HTA; 40.1% publications) (Figure 3)

Figure 4: Regions utilizing Nordic RWD<sup>#</sup>

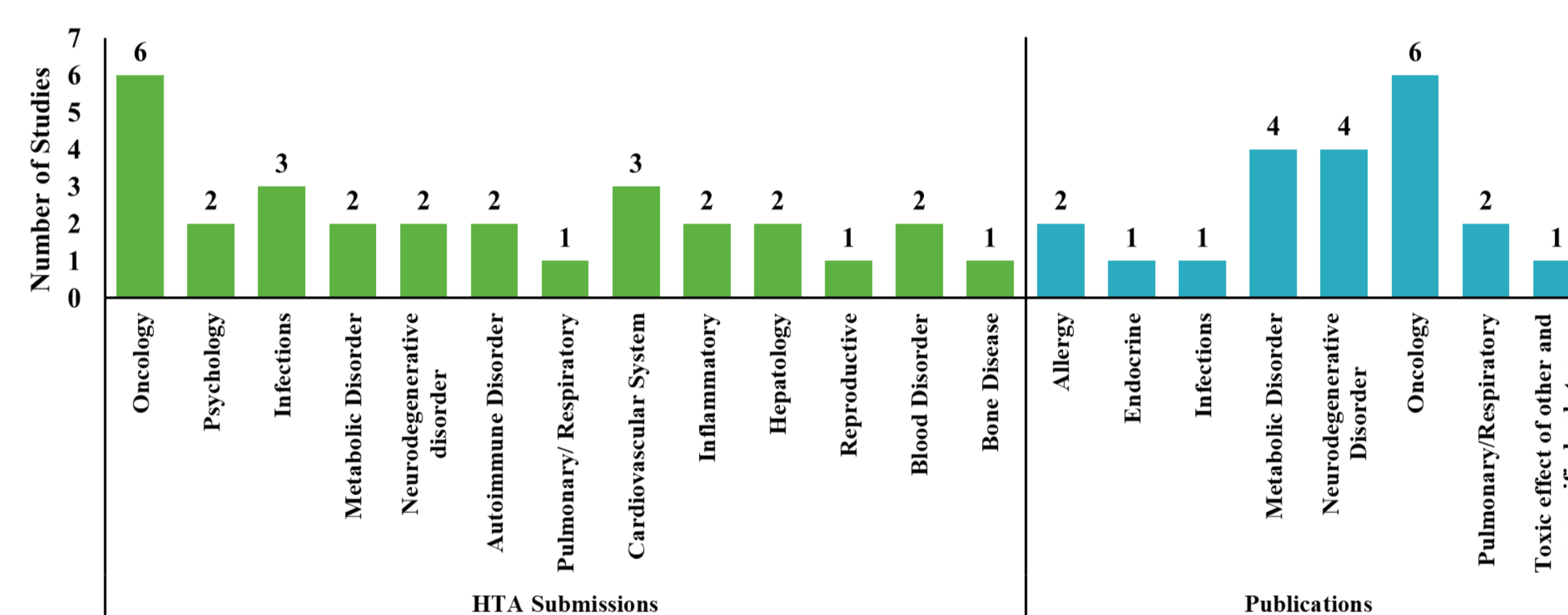


<sup>#</sup>Regions utilizing Nordic RWD was reported in all HTA submissions but in 22 publications

<sup>#</sup>Some publications reported >1 region

Please note: Asia/Pacific includes Australia, Japan, South Korea, and Singapore

Figure 5: Disease categories<sup>#</sup>

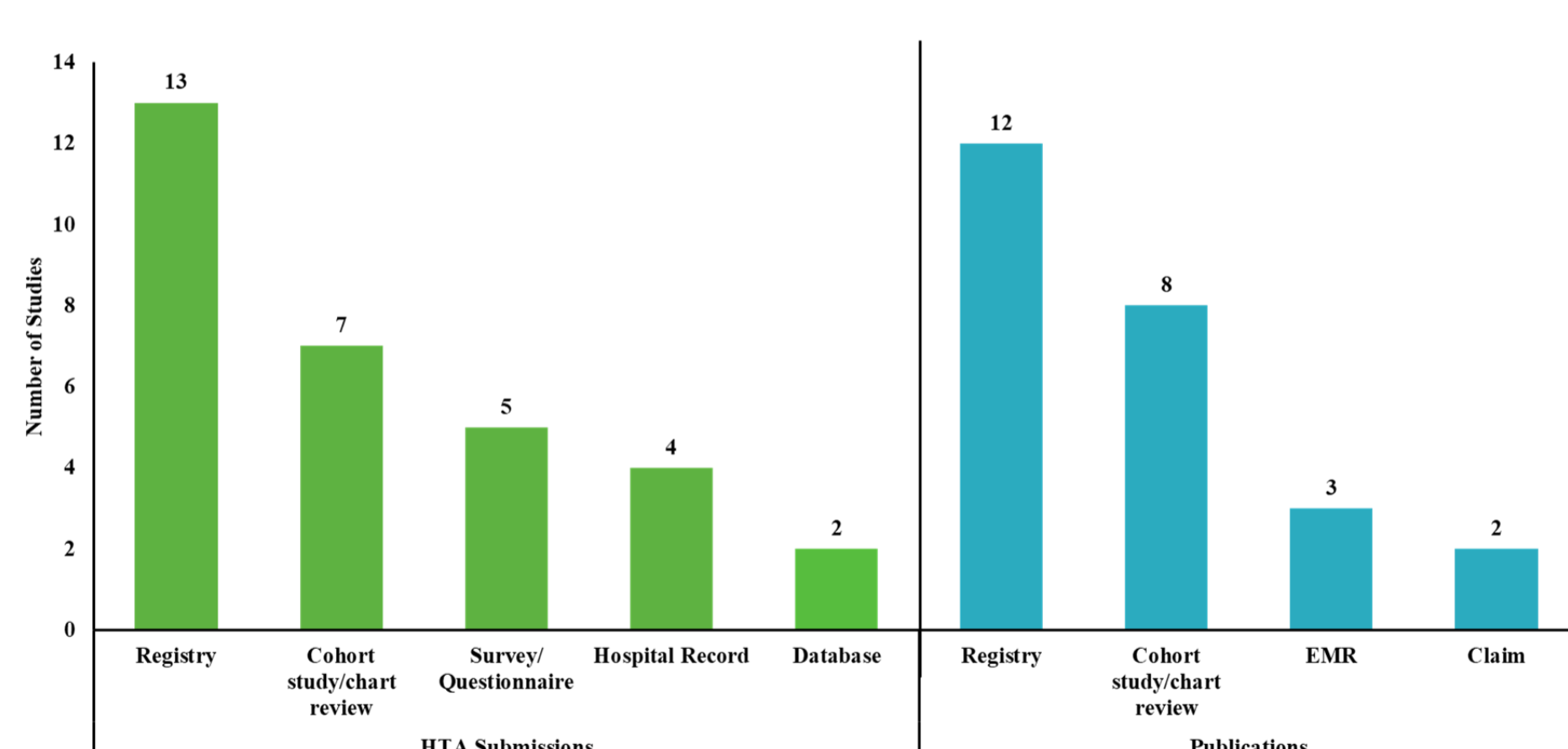


<sup>#</sup>Disease category was reported in all HTA submissions but in 20 publications

<sup>#</sup>Some records reported >1 disease category

- In-depth analysis of publications revealed that the top two regions utilizing the Nordic RWD were Europe (outside Nordic) and the US (Figure 4)
- Oncology was the most frequently reported disease area (6 in both categories)
- Infections and CVD were second highest reported disease areas in HTA submissions (4 each)
- Metabolic and neurodegenerative disorders were second highest reported disease areas in publications (3 each) (Figure 5)

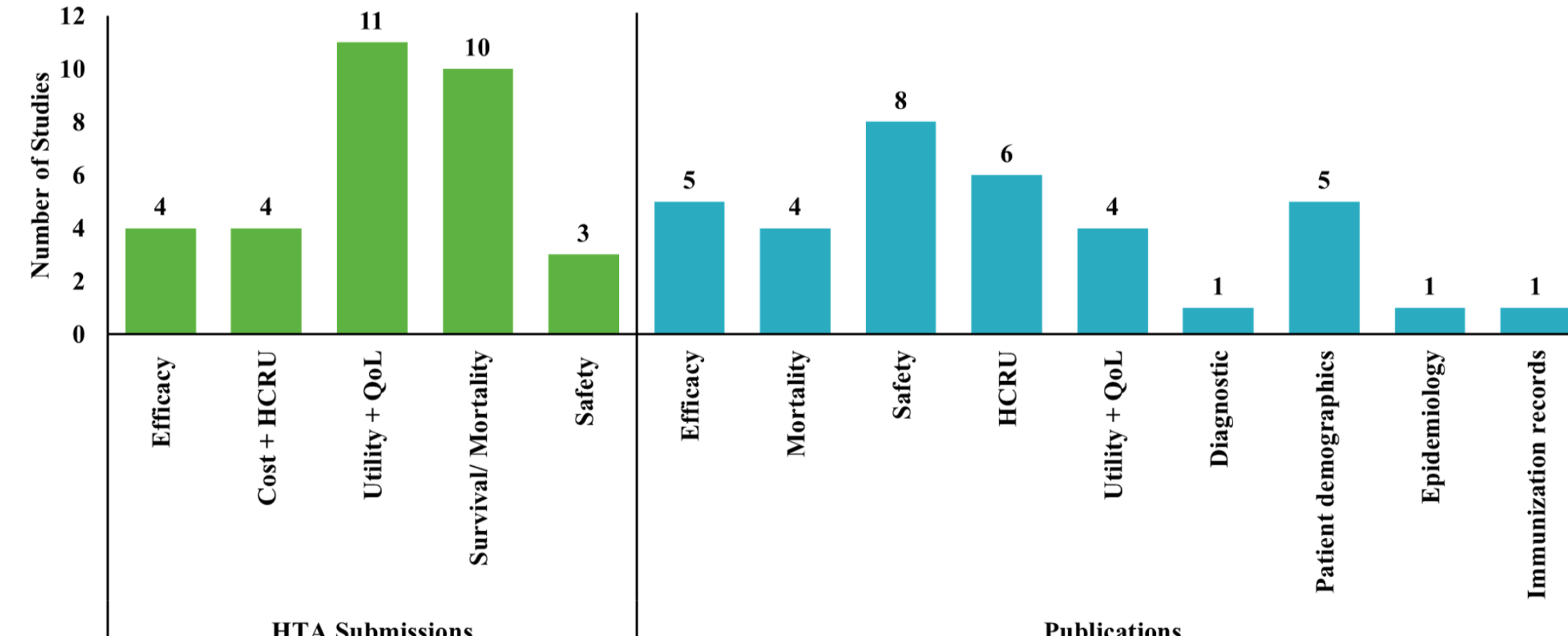
Figure 6: Sources of data<sup>#</sup>



<sup>#</sup>Source of data was reported in all HTA submissions but in 19 publications

<sup>#</sup>Some records reported >1 source of data

Figure 7: Type of outcomes reported<sup>#</sup>



<sup>#</sup>Type of outcomes was reported in all HTA submissions but in 23 publications

<sup>#</sup>Some records reported >1 outcome

- In HTA submissions, national administrative and disease registers were the most frequently reported RWD sources (Figure 6) followed by cohort studies/chart reviews
- In publications, disease-based registers were most frequently used data source, and most of the cohort studies/chart reviews were prospective (62.5%) in nature
- A wide spectrum of outcomes from Nordic registries were utilized at a global level. Utility/QoL (37.9%) and safety (34.7%) were the most common outcomes as per the evidence from HTAs and publications, respectively (Figure 7)

## Conclusions

- The evidence from the current review indicates global usage of Nordic RWD in various settings and disease areas. This encourages considering the Nordic RWD in support of HTA submissions, regulatory applications, and post-approval requirements, globally
- There is a lack of availability of guidelines in usage of RWD across the geographies and mapping of data from one region to the other. This calls for additional collaborative efforts between stakeholders in the industry, data holders, and regulatory authorities

**Abbreviations:** CADTH: Canada's drug and health technology agency; CVD: Cardiovascular disease; EMR: Electronic medical record; EU: European Union; HCRU: Healthcare cost and resource use; HTA: Health technology assessment; NICE: National institute for health and care excellence; PRISMA: Preferred reporting items for systematic reviews and meta-analyses; QoL: Quality of life; RWD: Real-world data; SLR: Systematic literature review; TI/AB: Title/Abstract

### References:

- Nordic statistics database. Available at: <https://www.nordicstatistics.org/news/population-forecasts-the-demographic-future-of-the-nordic-region/>
- Smith Jervelund S, De Montgomery CJ. Nordic registry data: value, validity and future. *Scandinavian Journal of Public Health*. 2020;48(1):1-4.
- Laugesen K, Ludvigsson JF, Schmidt M, Gissler M, Valdimarsdottir UA, Lunde A, Sørensen HT. Nordic Health Registry-Based Research: A Review of Health Care Systems and Key Registries. *Clin Epidemiol*. 2021;13:533-554.