

# Increasing patient access in Scandinavia through Outcome Based Agreements: Can the Spanish model be replicated?

HTA197

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## Background

Outcome-based agreements (OBAs) allow using real-world evidence to facilitate patient access to innovative therapies with high associated uncertainties. Whilst Spain (a decentralized healthcare system with similarities to Scandinavian regional payer systems) has introduced OBAs, Scandinavia is lagging behind despite a history of robust registry infrastructure. This study aimed to compare uncertainties highlighted by Scandinavian HTAs for therapies covered by OBAs in Spain, and to identify facilitators allowing OBA implementation in Spain potentially relevant for Scandinavian countries.

## Methods

- OBAs implemented in Spain between January 2017 and June 2022 were retrieved from PubMed, BIFIMED/VALTERMED and ISPOR databases. Products covered by OBAs in Spain were screened in Denmark, Norway and Sweden to identify corresponding HTA reports. These reports were subsequently evaluated to collect (a) reimbursement decision and (b) uncertainties identified by Scandinavian payers (mitigated by OBAs in Spain).
- A targeted literature review (TLR) was performed in the same databases to identify publications analyzing OBA implementation in Spain. Lastly, a thematic analysis of the TLR publications was performed to identify key facilitators for OBAs implementation in Spain.

## Results

- 19 OBAs were identified in Spain. Most (17/19) of the indications covered by OBAs in Spain were also assessed through HTAs in all of Scandinavia.
- Reimbursement was granted in all cases in Norway (17/17) and Sweden (17/17), but not in Denmark (10/17) (Figure 1).
- Long term-efficacy was identified as the most common source of uncertainty in Spanish OBAs and Scandinavian HTA reports (Figure 2), and the most common therapeutic area covered was oncology (11/17).
- The thematic analysis of the TLR identified 3 key facilitators for OBAs implementation in Spain (Figure 3).

Figure 1: Scandinavian HTA assessments of products covered by OBAs in Spain

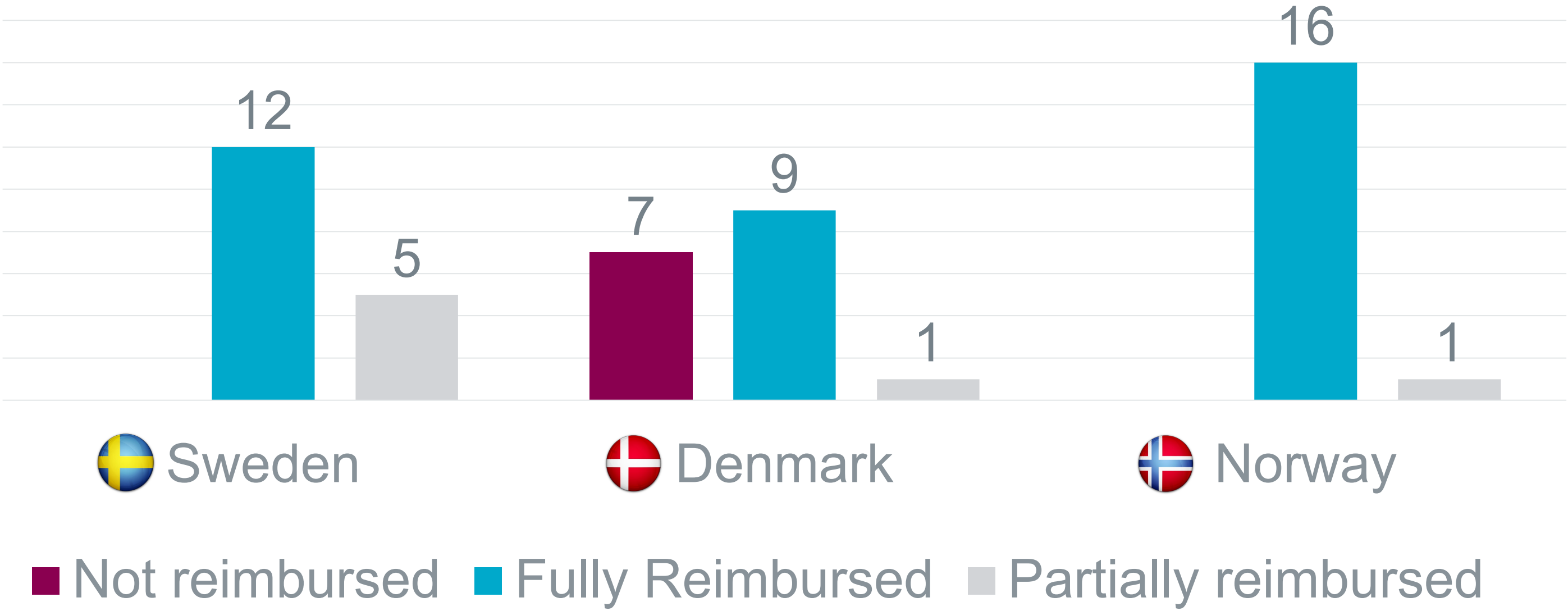


Figure 2: Uncertainties mitigated by OBAs in Spain also identified across Scandinavian HTA reports, frequency

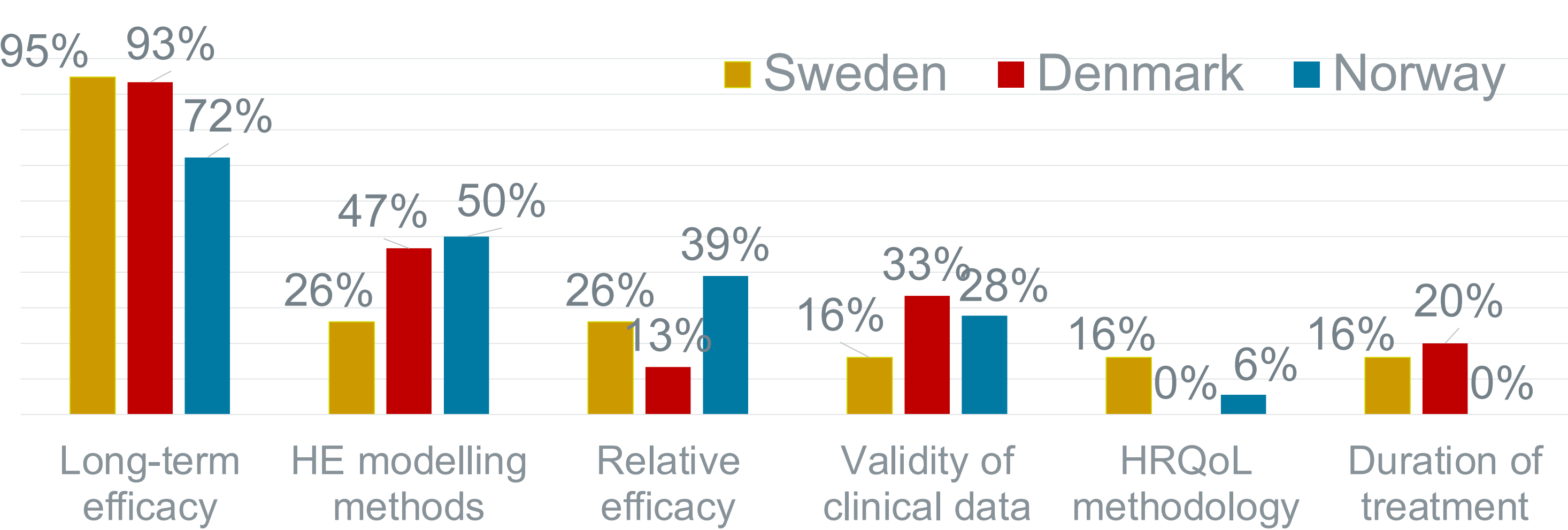
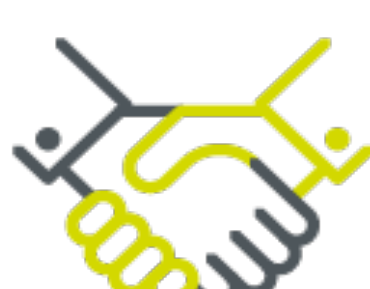


Figure 3: Key facilitators for OBAs implementation in Spain



**Data-collection system** (VALTERMED) that leverages existent infrastructure



**Systematic accountability** for data-collection/processing



**Scaling approach** for OBA implementation championed by regional governments

## Discussion and conclusions

- The Spanish model for OBAs provides an opportunity for increasing patient access in Denmark. Nonetheless, the potential benefits for Norway and Sweden are attractive mostly for payers, who can implement OBAs as a mechanism to share the uncertainty-related risks with manufacturers.
- Scandinavian countries are known for robust and high-quality registry infrastructures that facilitates the feasibility of implementing OBAs, similar to the Spanish experience of developing VALTERMED.
- The introduction of the EU Joint Clinical Assessment (JCA) is likely to impact the time from market approval to patient access. Having a national OBA structure at place can support the adoption of JCA recommendations in national HTA in a timely manner.
- Innovation of advanced therapeutic products is rapidly progressing; therefore, innovative payment models are needed to mitigate payer risks. Further research is suggested to explore options that ensures timely patient access while satisfying payer preference in the Scandinavian setting.

## REFERENCES

[1] HTA webpages SHEA 23 poster: ISPOR poster Parexel (Justyna Tomassy) Databases SHEA poster Articles extracted. [2] NT council Database: <https://janusinfo.se/> [3] TLV Database: <https://www.tlv.se/> [4] DMC Database <https://medicinraadet.dk/> [5] CatSalut, Laura G. 2022 <http://doi.org/https://doi.org/10.1016/j.jval.2021.10.010> [6] Generalitat de Catalunya, MAYO 2014 Catalunya. [7] VALTERMED: <https://www.sanidad.gob.es>