Comparative analysis of accessibility and time to reimbursement to oncology treatments with substantial benefit across Europe: focus on breast, lung, prostate, and colorectal cancer

Buijsman T.[1*], Van Wijk M.[2*], Mokri H.[2] , Ruijs T.Q.[2,] Uyl-de Groot C.A.[3,4], Tjan-Heijnen V.C.G.[5], Sinke A.P.[1]

[1] Gilead Sciences, Amsterdam, The Netherlands; [2] IQVIA, Amsterdam, the Netherlands; [3] Erasmus School of Health Policy and Management, Erasmus University Rotterdam, Rotterdam, the Netherlands, [4] Institute for Medical Technology Assessment (IMTA) [5] Maastricht University Medical Centre+, Division of Medical Oncology, Maastricht, the Netherlands. [*] Both authors contributed equally to this work.

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SHINe INEQUITIES IN ACCESS TO INNOVATION

Conclusions

- Access to cancer treatments with substantial benefit as defined by the European Society for Medical Oncology (ESMO) varies significantly across countries in Europe. Our analysis of **46 drug-indication combinations** approved for use in the European Union (EU) between 2016 and 2023 shows that access ranged substantially across eleven selected countries, from **100% in Germany to 67% in Ireland.**
- The **median time to reimbursement (TTR) across** all selected countries **ranged from 1.0 month in Germany to 22.8 months in Ireland.**
- These findings highlight **inequalities in access to cancer treatments with substantial benefit across Europe**, both between countries and across cancer types. Addressing these disparities is essential to ensure timely and equitable access to the most innovative treatments for all patients.

Plain Language Summary

- Access to new and effective cancer treatments can vary widely across Europe. In this study, we looked at how quickly and how often cancer drugs with substantial clinical benefit – based on the European Society for Medical Oncology (ESMO) criteria – are made available to patients in eleven European countries.
- This study looked at 46 treatments for breast, lung, prostate, and colorectal cancer that received approval in the European Union between 2016 and 2023.
- Some countries, like Germany, made all of them available quickly. Others, like Ireland, offered fewer and took much longer – up to nearly two years.
- **Patients across Europe face unequal access to important cancer treatments depending on where they live and what type of cancer they have.**

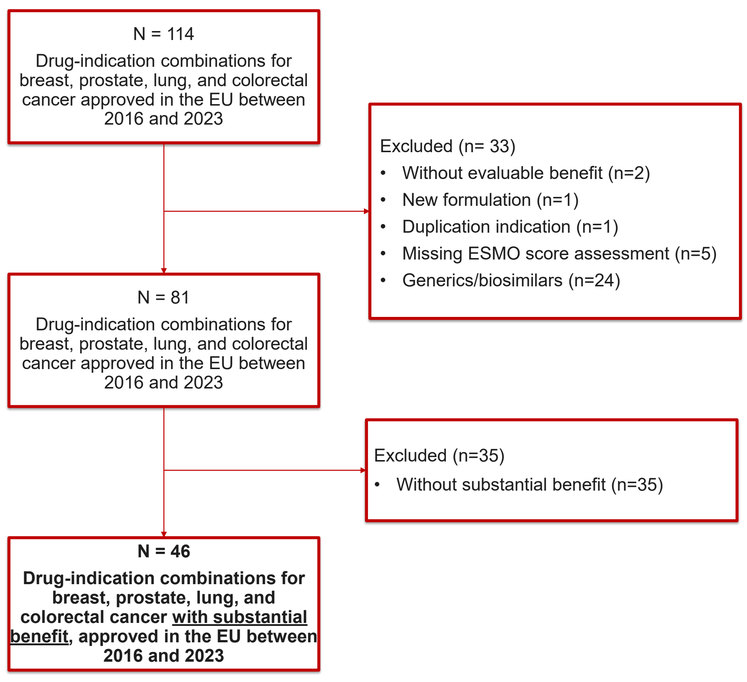
Introduction

- As cancer incidence continues to rise, timely and equitable access to innovative cancer treatments is critical for improving patient outcomes, especially for innovative treatments with substantial benefit.
- The European Society for Medical Oncology (ESMO) developed the ESMO-Magnitude of Clinical Benefit Scale (MCBS) to "facilitate improved decision-making […], promote the accessibility and reduce inequity of access to high value cancer treatments".[1]
- The EFPIA Patients W.A.I.T. indicator surveys, however, consistently reveal strong variation across Europe in both the rate of accessibility, measured by the number of medicines reimbursed, and the time to reimbursement (TTR).[2,3]
- Thus far, no studies have reported on the access and TTR of drugs with a substantial benefit – as defined by ESMO-MCBS – for some of the most prevalent solid cancer types.

Methods

- A retrospective analysis was conducted using publicly available data on health technology assessments (HTA) and reimbursement decisions from eleven European countries.
- The analysis included drug-indication combinations (hereafter: DIC) with substantial benefit for breast, lung, prostate, and colorectal cancer that received EU marketing authorization between 2016 and 2023.
- Only treatments with substantial clinical benefit – defined by an ESMO-MCBS score of 4/5 (non-curative) or A/B (curative) were included.
- Supportive care products, biosimilars and previously approved medicines introduced only in a different formulation were excluded.
- The TTR is defined as the time in months between the date of EMA marketing authorization and the date of (conditional) reimbursement in the respective country.
- Survival analysis was used to analyze TTR to also include the non-reimbursed products at cut-off date (30 September 2025).

Figure 1. Flowchart of selection of drug-indication combinations for current analysis



Results

- A total of **114** DICs were approved for use between 2016 and 2023 of which 42 (36.8%) was excluded due to not having a substantial benefit, not having evaluable benefit, new formulation or no ESMO score available **(Figure 1)**.
- In the current analysis, a total of **46** DICs with substantial benefit were included, most for lung cancer (25/46), followed by breast (14/46), prostate (4/46), and colorectal cancer (3/46) **(Table 1)**.

Table 1. Overview of included drug-indication combinations with substantial benefit approved for use in th EU between 2016 and 2023

Primary disease	Number of drug-indication combinations
Breast cancer	14
Colorectal cancer	3
Lung cancer	25
Prostate cancer	4
Total	46

- The access to DICs varied by country and cancer type. The number of reimbursed DICs was the highest in Germany (100%), Sweden (93%), and Italy (89%). The Netherlands (72%), Denmark (70%), and Ireland (67%) had the lowest number of reimbursed DICs.
- The reimbursement rate for breast cancer ranged from 64% in the Netherlands and Ireland to 100% in Sweden, Italy, and Germany. For lung cancer, the reimbursement rate ranged from 68% in Ireland and Denmark to 100% in Germany. The percentage of reimbursed DICs was generally higher for breast cancer than lung cancer, except for the Netherlands (64% vs. 76%) and Ireland (64% vs. 68%) **(Figure 2)**.
- The median TTR for all DICs for all cancer types notably varied between countries. After Germany, Sweden and Scotland had the shortest TTR (respectively 1.0, 7.2 and 9.3 months), while France and Ireland had the longest TTR (19.3 and 22.8) **(Figure 3).**

Figure 2. Access to drug-indication combinations, stratified by cancer type

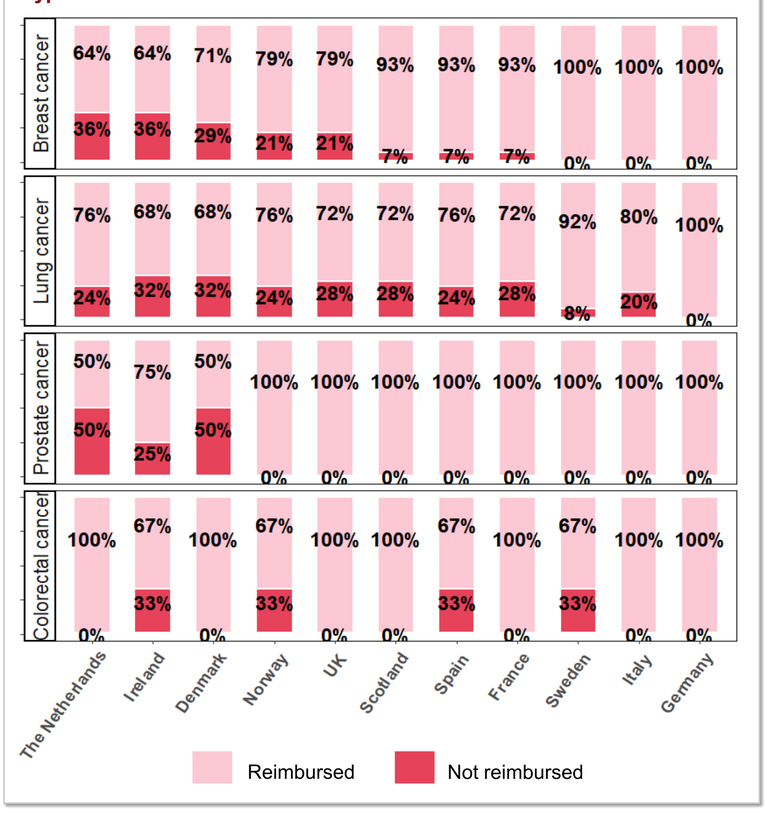
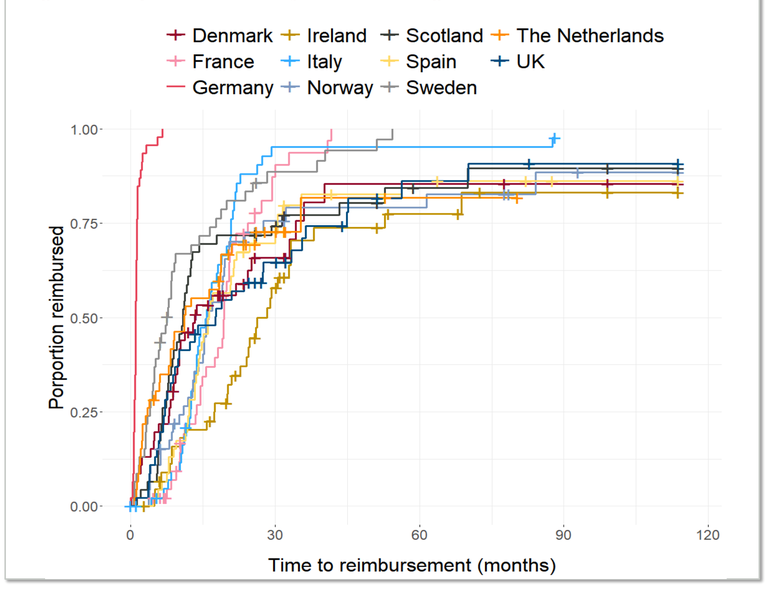
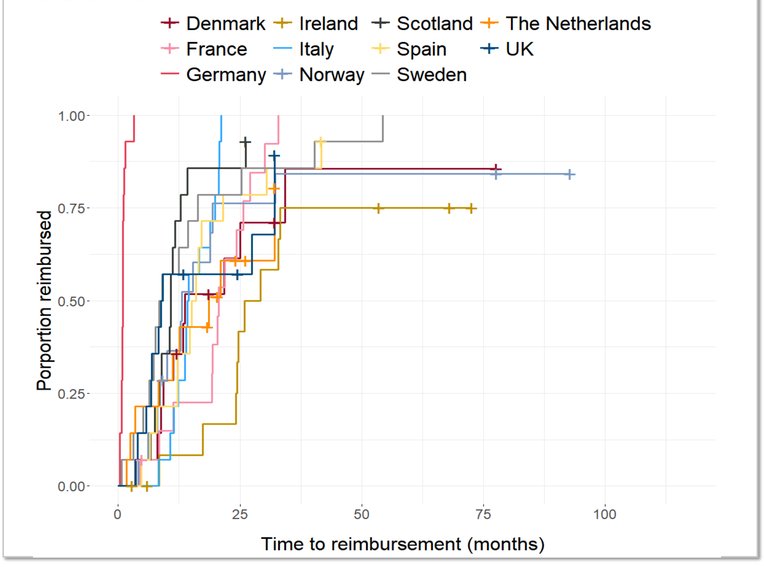


Figure 3. Kaplan-Meier analysis for all drug-indication combinations



- The median TTR for breast cancer drugs were longest in Ireland (25.3 months), The Netherlands (18.5), and France (15.2), and shortest in Germany (1.0), UK (9.0), and Sweden (8.8) **(Figure 4)**.
- In the Netherlands, breast cancer therapies had a substantially longer TTR than lung cancer therapies (18.5 vs. 8.9 months) which seems to increase over time. This pattern was also observed in Denmark (13.5 vs. 10.1) and Sweden (8.8 vs. 5.0) (data not shown).

Figure 4. Kaplan-Meier analysis for drug-indication combinations for breast cancer



Discussion

- This study demonstrates that substantial clinical benefit – as defined by ESMO-MCBS – does not necessarily translate into equitable patient access across Europe.
- Despite the recognized value of these cancer treatments, heterogeneity persists with certain countries such as the Netherlands, Denmark, and Ireland experiencing prolonged reimbursement timelines and lower accessibility in comparison to other countries like Germany and Italy.
- The findings from current analysis are in line with previous research such as published by Post *et al. (*2023) and the EFPIA Patient W.A.I.T. indicator surveys.[2-4]

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Correspondence: Thomas Buijsman (thomas.buijsman@gilead.com) and Max van Wijk (max.vanwijk@iqvia.com)

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