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Forgone health

from restricted oncology access under most-favored-nation pricing

A two-margin framework with a breast cancer illustration

UPDATED ABSTRACT

Analysis revised since submission: four-country comparison, US launch as starting point, population-level metrics. Figures provisional and illustrative.

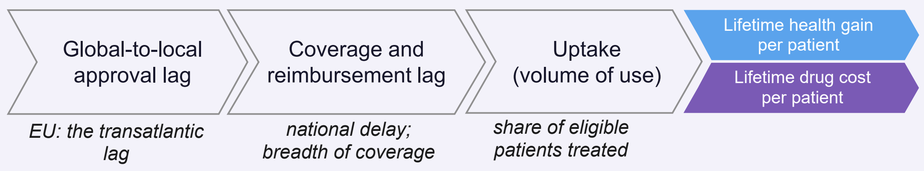
Objectives. US most-favored-nation (MFN) pricing gives manufacturers an incentive to delay or restrict European launches, while EU Joint Clinical Assessment (JCA) adds new demands at launch. We quantify health forgone when access lags, distinguishing an availability margin (whether and when a drug is reimbursed) from a coverage and utilization margin (how many eligible patients are treated).

Methods. Counterfactual: German-path uptake starting at US approval. Monthly shortfalls to December 2025 were split into transatlantic lag, national reimbursement delay, lower utilization and coverage restriction, for ribociclib in Germany, the UK, Poland and Romania, separately in metastatic (MBC) and early (EBC) breast cancer. Lifetime gains per patient came from published cost-effectiveness analyses.

Results. Equivalent healthy lifetimes lost per million: Germany 0.9, UK 2.7, Poland 4.9, Romania 6.1. Poland and Romania realized ~35% of the attainable gain (UK 73%, Germany 91%). The transatlantic lag was nearly all of Germany's loss but 12–13% in Poland and Romania.

Conclusions. Access delays already impose income-related health losses in Europe. Converting months of delay into forgone health lets emerging evidence on MFN- and JCA-related launch changes be judged in health terms.

FRAMEWORK: ONE ACCESS CASCADE, TWO LEDGERS



Realized health for the country's patients =
availability × access × uptake × health gain per patient

Realized contribution to global R&D =
availability × access × uptake × cost per patient

Availability ("extensive") margin = the two lags. Coverage and utilization ("intensive") margin = breadth of coverage plus uptake. The same access failures reduce both ledgers; price enters contribution directly and health only through access.

METHODS AND DATA

Design. Retrospective counterfactual for ribociclib plus endocrine therapy, from US FDA approval (metastatic March 2017; early September 2024) to 31 December 2025. In the counterfactual, every country follows Germany's uptake path from the FDA date: a 12-month linear ramp to a steady state of 30% of eligible patients (metastatic) or 35% (early).

Decomposition. Each month, forgone patients = monthly eligible patients × the gap between two uptake curves. Summed to December 2025, these give four additive components:

1. *Transatlantic lag: FDA to EC approval (5.3 months metastatic; 2.3 early).*
2. *National delay: EC approval to national reimbursement.*
3. *Coverage restriction: UK early disease, partial-label access April–August 2025 (53% of label).*
4. *Lower uptake: national steady-state uptake relative to Germany (UK 0.9, Poland 0.6, Romania 0.5).*

Components 1–2 reduce availability, 3 coverage and 4 uptake: availability × coverage × uptake.

Eligible patients per year. Metastatic: incident cases × (de novo metastatic share, 6–10% by country, + 12% recurrence) × 70% HR+/HER2−. Early: non-metastatic incident cases × 70% HR+/HER2− × 40% high-risk (NATALEE label).

Health per patient. One set of lifetime gains applies to all four countries, so cross-country differences reflect access alone.

Lifetime gain per treated patient (applied to all four countries)	Life-years	QALYs
MBC, base (range)	1.05 (0.85–1.50)	0.85 (0.70–1.20)
EBC, base (range)	0.85 (0.69–1.23)	0.70 (0.67–0.98)

Ribociclib + endocrine therapy vs endocrine therapy alone; from published cost-effectiveness models (see references).

Metrics

- QALYs and life-years forgone
- Equivalent healthy lifetimes (EHL) lost per million population: QALYs ÷ 26 (discounted QALYs in a newborn's lifetime at 3%)
- Share of attainable gain realized

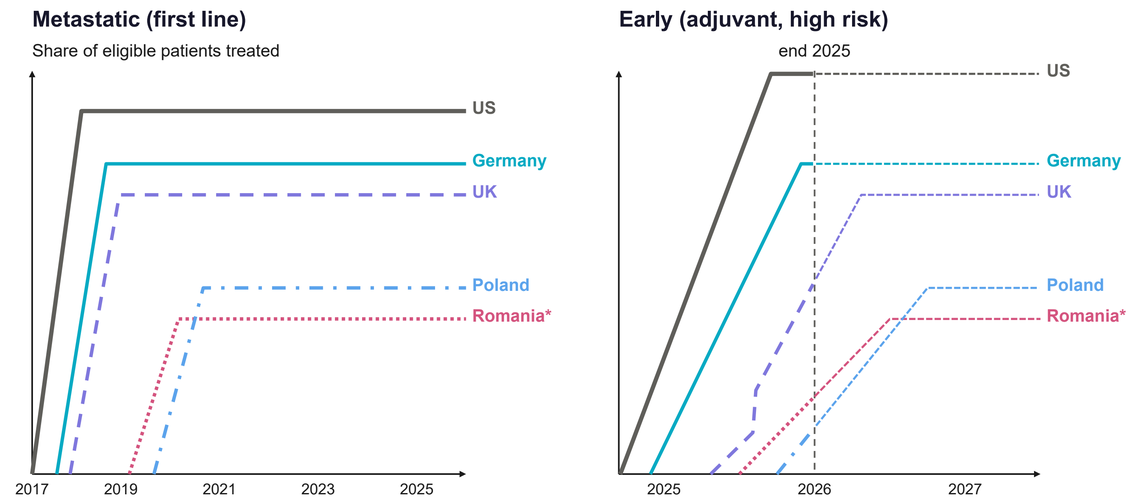
CONCLUSION

- Access delays already impose measurable, income-related health losses in Europe.
- The margins that shrink a country's contribution to global R&D also cost its own patients health.
- Per product the loss is modest per million; the concern is its repetition across every launch that MFN and JCA touch

NEXT STEPS

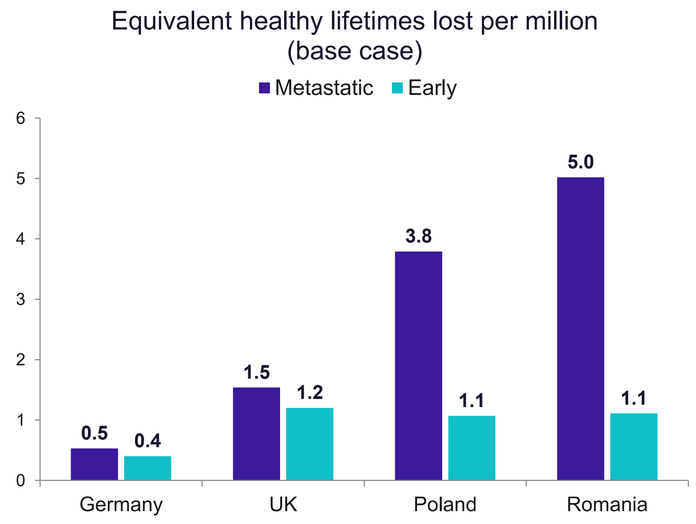
Class-level calibration (e.g., Polish NFZ patient counts, English prescribing data); per-launch and per-year metrics; MFN and JCA delay and non-launch scenarios.

Staggered uptake: estimated access to end of 2025



Illustrative—not to scale. *Start dates from regulatory and reimbursement records; plateaus are model uptake assumptions relative to Germany. Early disease: solid = observed window, thin dashed = projection. UK early disease: partial coverage Apr–Aug 2025. *Romania dates provisional.*

Health forgone by country, US launch to end of 2025



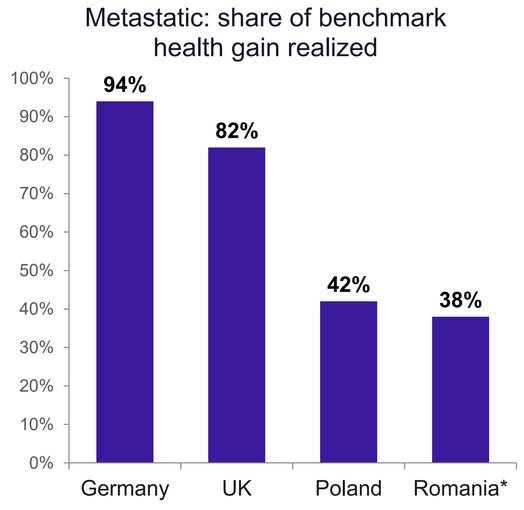
Country inputs

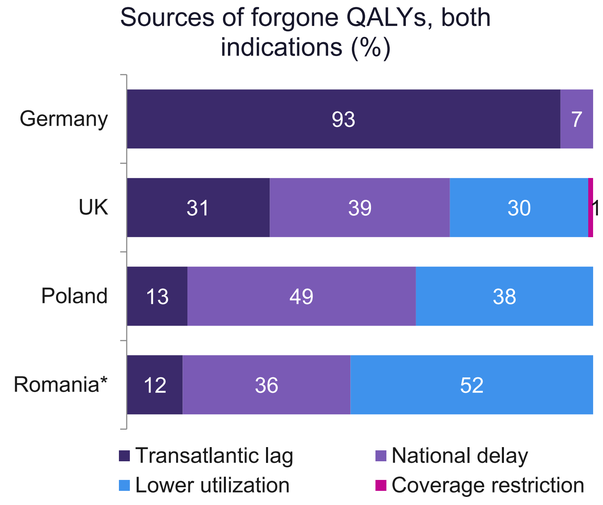
Country	Population (millions)	Incident breast cancers / yr	MBC-eligible patients / yr	EBC-eligible patients / yr	GDP per capita, PPP (int'l $, 2025)	% of US
United States	341.8	—	—	—	90,027	100
Germany	83.5	70,000	8,820	18,424	75,407	84
United Kingdom	69.3	56,800	7,157	14,950	64,606	72
Poland	37.5	21,554	3,018	5,552	54,262	60
Romania*	19.0	12,300	1,894	3,100	50,895	57

*MBC: first-line HR+/HER2− advanced breast cancer; EBC: high-risk HR+/HER2− early breast cancer. US shown as the launch reference; not modelled for patients. Incidence: GLOBOCAN 2022 (Germany, Romania), CRUK (UK), Polish National Cancer Registry 2022. GDP per capita at purchasing power parity, current international $, and US population: World Bank, World Development Indicators. *Romania inputs provisional.*

Losses rise across the income gradient; metastatic losses dominate because that window is ~9 years long.

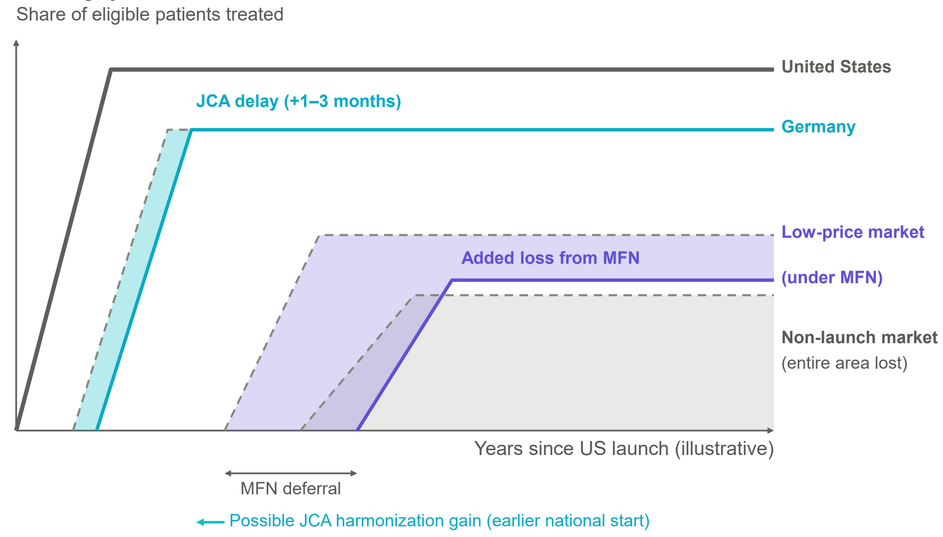
How much of the attainable gain was realized, and why not





The transatlantic lag is nearly all of Germany's loss but a small share further down the income gradient, where national delay and lower utilization dominate.

Looking ahead: how MFN and JCA could shift a future launch



Each shaded area is what the model computes. A scenario is a change in start date, plateau or both, so the framework prices behaviour already being reported without predicting it.

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LIMITATIONS

- Gross forgone health; opportunity cost of spending not netted out.
- Uptake assumed pending calibration to utilization data; ribociclib-specific rather than class-level use.
- Modelled lifetime gains; EBC survival benefit extrapolated.

SELECTED REFERENCES

- Hortobagyi GN, et al. N Engl J Med. 2022;386:942-950 (MONALEESA-2 OS).
- CDA-AMC. Ribociclib (early breast cancer) reimbursement recommendation, 2026.
- NICE TA496 (2017); NICE TA1086 (2025).
- Ramagopalan S, et al. J Comp Eff Res. 2026 (launches after MFN and JCA).
- AOTMiT. Kisqali analysis, 2025 (NFZ patient counts).
- Published ribociclib cost-effectiveness models (PMIDs on request).

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