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Are European Healthcare Systems Prepared for a Potential Rapid Rise in Radioligand Therapy Eligible Patient Numbers?

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KEY FINDINGS & CONCLUSIONS

- This research predicts a potential seven-fold increase in the number of RLT-eligible patients over the next decade and a five-fold increase in the number of treatment slots required, which will likely exhaust existing treatment capacities in EU-4 and the UK.
- While the RLT capacity gap will begin to emerge in 2026, it is expected to become more pronounced by 2029 in EU-4 and the UK.
- Given the challenges associated with scaling nuclear medicine facilities, urgent action is needed by healthcare systems decision-makers to safeguard future patient access and ensure continued excellence in cancer care.

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INTRODUCTION

- Pivotal trials have demonstrated that [^{177}Lu]Lu-DOTATATE (^{177}Lu-DOTATATE) and [^{177}Lu]Lu-PSMA-617 (^{177}Lu-PSMA-617) have a favorable benefit-risk profile in patients with advanced midgut neuroendocrine tumors and metastatic castration-resistant prostate cancer, respectively, compared with established therapies.[1,2]
- Regulatory approvals by EMA and FDA have expanded patient access to RLT significantly in the approved indications, paving the way for future development and registration of RLTs across additional cancer types.[3–7]
- An increasing number of clinical trials are ongoing to evaluate RLT in earlier stages of disease and in additional cancer types. As a result, the role of RLT—and nuclear medicine more broadly—in cancer care is expected to increase rapidly in the coming years.[8]
- To support the integration of RLT into clinical practice, we report patient eligibility estimates to help healthcare systems proactively plan and invest in nuclear medicine services, including estimating capacity to meet the potential rise in demand for advanced care.

METHODS

- Numbers of future potentially RLT-eligible patients were calculated based on indications for which RLT are currently approved or in advanced phase 2 and 3 trials (clinicaltrials.gov); cancer incidence (27 EU countries; ECIS; https://ecis.jrc.ec.europa.eu/) and prevalence (Germany, France, Italy, Spain [EU-4], and the UK; IHME); fractions of real-world patients (based on literature reports) with cancer subtype, stage, prior treatment; and proportions of cancers expressing the RLT targets (based on literature reports).
- Incidence and prevalence data were supplemented with data from the UK Haematological Malignancies Research Network (https://hmrn.org/) or from additional literature searches where data were unavailable for certain indications or cancer subtypes.
- Treatment capacity estimates were based on available nuclear medicine beds (adjusted to account for limits in staff availability and waste management, which can prevent full infrastructure utilization), the average length of hospital stay in each country, and treatment cycles (by product).
- Treatment capacity gap was calculated by subtracting the number of treatment slots required* from the number of treatment capacity slots available.

*derived by multiplying the eligible population numbers for each indication with the average treatment cycles needed (EMA or study protocol were used; if this information was not available an average of four cycles was assumed) among products targeting the same indication.

RESULTS

Incidence- and prevalence-based projected growth in patients eligible for RLT

- **Table 1** presents the projected increase in patients who may require treatment in nuclear medicine departments across individual EU member states and the UK, based on incidence data and, where available, prevalence data.
- Across the EU-27 countries, the estimated number of patients potentially eligible for RLT is projected to increase by approximately 140,000 to 200,000 between 2022 and 2035.
- Despite methodological differences, both approaches show strong alignment in projected growth, indicating that across the four largest EU countries, up to 127,800 additional patients per year (prevalence-based) may become eligible for RLT by 2033/35.

Table 1. Estimated growth in the number of patients eligible for RLT, across EU member states and the UK

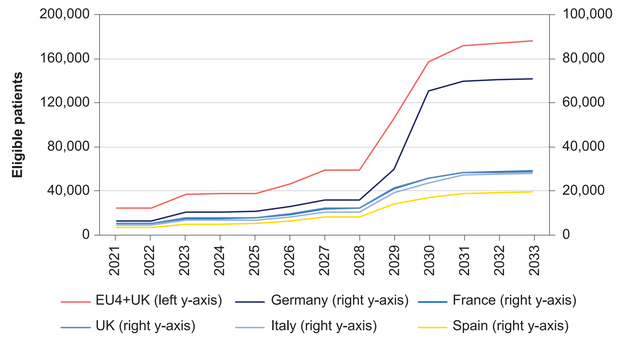
Country	Estimated increase in annual RLT-eligible patients by 2025, 2030, and 2035, compared to 2022		
	2022–2025	2022–2030	2022–2035
EU-27	7,400–16,100	47,900–86,800	143,500–201,800
Austria	100–300	900–1,600	2,600–3,600
Belgium	200–500	1,500–2,700	4,300–6,100
Bulgaria	< 100	500–800	1,200–1,700
Croatia	100–200	400–800	1,300–1,800
Cyprus	<100	100–200	300–500
Czechia	100–300	1,000–1,900	3,700–5,200
Denmark	100–300	700–1,300	2,100–2,900
Estonia	< 100	200–300	500–700
Finland	100–300	700–1,400	2,200–3,100
France	1,300–2,800	8,300–14,900	24,400–34,400
France (*)	**2,500**	**20,600**	**23,800**
Germany	1,500–3,200	9,400–17,000	28,100–39,600
Germany (*)	**4,300**	**59,000**	**64,600**
Greece	100–300	1,400–1,800	3,000–4,200
Hungary	100–300	900–1,600	2,800–3,900
Ireland	100–200	600–1,100	2,000–2,800
Italy	800–1,800	5,900–10,600	17,900–25,100
Italy (*)	**2,400**	**19,200**	**23,400**
Latvia	< 100	200 - 400	700 - 900
Lithuania	100–200	400–700	1,300–1,800
Luxembourg	< 100	100	200–300
Malta	< 100	100	100–200
Netherlands	300–600	1,900–3,300	5,300–7,500
Poland	500–1,100	3,400–6,100	9,900–13,900
Portugal	200–400	1,100–2,000	3,100–4,400
Romania	200–500	1,500–2,700	4,200–5,900
Slovakia	100–200	500–1,000	1,800–2,500
Slovenia	100	300–500	800–1,100
Spain	800–1,700	4,900–9,000	15,500–21,800
Spain (*)	**1,500**	**13,400**	**16,000**
Sweden	300–600	1,400–2,700	4,100–5,900
UK (*)	**2,700**	**20,500**	**23,700**
EU-4	3,700–9,500	26,600–49,100	83,900–118,400
EU-4 (*)	**10,700**	**112,200**	**127,800**

Rows marked with (*) present cancer prevalence data (obtained from the IHME database); in these cases, the final column shows the projected increase from 2022 to 2033. All other figures are based on incidence data (obtained from the ECIS database) with the lower and upper bound estimates reported. The increase is calculated relative to 2022 as the reference year, and values are rounded to the nearest hundred.

Prevalence-based estimation of patients potentially eligible for RLT in France, Germany, Italy, Spain and the UK

- For all indications, the number of eligible patients in the EU-4+UK is estimated to rise from 24,550 in 2022 to 176,020 in 2033 (**Figure 1**).
  - Year-on-year increases in the eligible population are primarily driven by usage of authorized therapies earlier in the stage of disease and the anticipated availability of new products for new indications, with a smaller contribution from the rising prevalence of existing indications.

Figure 1. Patients eligible for RLT between 2021 to 2033, by country and combined (EU-4+UK)

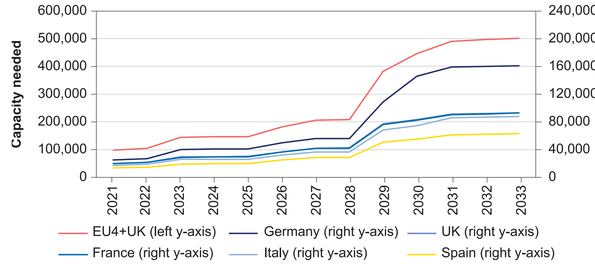


The number of eligible patients was calculated with the estimation of year of product approval, prevalence figures for indication and marker expressions, as well as correction factors for disease characteristic group and line of treatment.

Treatment slots required

- Treatment capacity is measured in treatment slots, which in this case refers to the use of treatment rooms equipped with chairs/beds to administer a single dose of the radiopharmaceutical. A single patient may require up to six doses.
- The number of RLT treatment slots required is expected to increase from 104,754 in 2022 to 501,543 in 2033, corresponding to almost a five-fold increase (**Figure 2**).
- Germany shows the highest demand for RLT, with 27,379 treatment slots needed in 2022 and 161,182 projected by 2033.

Figure 2. Capacity required in treatment slots for RLT between 2021 to 2033, by country and combined (EU-4+UK)

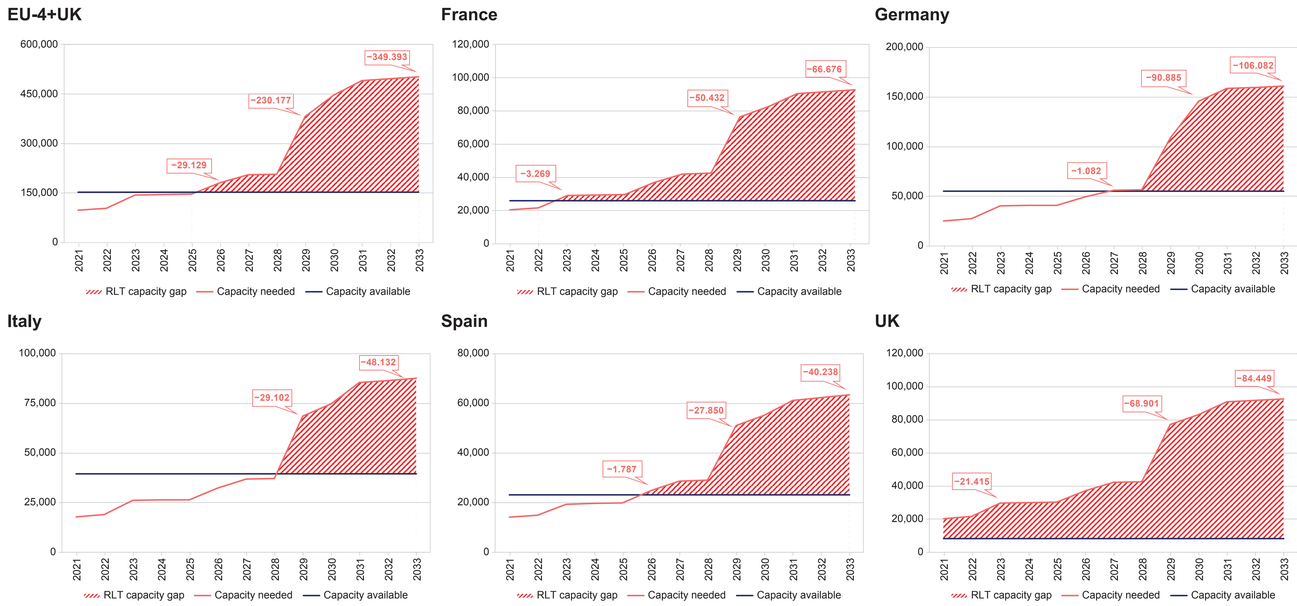


Includes patients eligible for RLT as well as the average treatment cycles required per indication.

RLT capacity gap

- The capacity gap is calculated by assessing available infrastructure in terms of treatment rooms, alongside hospitalization duration and current usage for established therapies (e.g., thyroid treatments with ^{131}I, bone pain palliation, radioembolisation, and radiosynovectomy) as outlined for high-income countries.[9] This helps estimate free capacity and compare it with the growing demand for RLTs.
- Between 2021 and 2024, existing RLT capacity in the EU-4+UK was sufficient to meet projected demand, ensuring adequate availability to support treatment needs across all five countries (**Figure 3**).
- In 2026, a capacity gap in RLT emerges representing a 16% shortfall between needed and available capacity.
- By 2033, the gap is projected to widen significantly to 349,393 missing treatment slots, meaning that the need in the EU-4+UK will exceed the available capacity in 2021 by more than a factor of two, unless upscaling is initiated in due course.

Figure 3. RLT capacity gap in treatment slots for RLT between 2021 to 2033, by country and combined (EU-4+UK)



Estimated infrastructure RLT capacity gap was measured by deducting the capacity required in RLT treatment slots (dark red line) from the capacity available for RLT treatment slots (shaded red area). These figures are corrected by a capacity buffer that tackles the fact that it is not possible to fully utilize the infrastructure to its potential as a result of staff availability and waste management constraints. This capacity buffer is assumed to be 15% and applied for each country.

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Abbreviations

ECIS, European Cancer Information System; EMA, European Medicines Agency; FDA, Food and Drug Administration; IHME, Institute for Health Metrics and Evaluation; PET, positron emission topography; RLT, radioligand therapy.

Disclosures

UH, MG, RC declare no conflict of interest; the contribution of DH and PP was funded by Novartis, CF and PK received consulting fees from Novartis (unrelated to the present work), LS, AP, and PP are employed by Novartis.

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