

## EARL Theranostics Centre of Excellence certification: raising the standard of targeted radionuclide therapy care in Europe and beyond

The European Association of Nuclear Medicine Forschungs GmbH (EARL) has long supported standardisation and quality assurance in clinical molecular imaging and radionuclide therapies through accredited benchmarking programmes. In 2023, EARL expanded this mission by launching the Theranostics Centre of Excellence (CoE) network, designed to promote a harmonised, high-quality framework for centres delivering targeted radionuclide therapy (TRT). As this field evolves rapidly and its clinical demand increases, the need for robust, evidence-based quality structures becomes stronger.

The Theranostics CoE programme was developed to provide a clear, scalable pathway that guides centres in achieving and sustaining high standards of theranostic practice, regardless of their size, indication spectrum, or organisational model. Rather than a single certification step, the CoE framework establishes a continuum of quality standards. Centres can demonstrate compliance with essential requirements while also having the opportunity to progress toward more advanced competencies as their clinical, technical, and organisational capabilities grow.

Following the successful pilot phase of the Level 1 (“Qualified”) Theranostics CoE programme, we recently introduced the Level 2 certification, the “Advanced Theranostics Centre of Excellence”. In this letter, we would like to (1) briefly outline the principles of the EARL Theranostics CoE framework; (2) articulate why a tiered system is essential for ensuring safe, reproducible, and patient-centred theranostic care across Europe and beyond; and (3) describe the evidence and analysis that led to the implementation of more stringent requirements in Level 2.

### 1. Background and motivation

The theranostic principle has been embedded in nuclear medicine for decades [1–3]. Over the last 10–15 years, however, the introduction of agents with marketing authorisation such as [<sup>177</sup>Lu]Lu-DOTATATE and [<sup>177</sup>Lu]Lu-PSMA-617 has catalysed exponential clinical visibility and relevance [4,5]. Therapeutic options have further expanded with new β-emitters, α-emitters (e.g., [<sup>225</sup>Ac]-labelled agents), and novel targeting vectors [6]. As a result, TRT services now range from single-indication, low-volume units to large, multidisciplinary programmes providing complex theranostic pipelines.

This diversity represents both a strength and a challenge. The EARL Theranostics Level 1 certification provided a necessary first step in the continuum of quality standards: identifying centres capable of delivering safe, standardised TRT using established radiopharmaceuticals. However, our early analysis of Level 1 applicants and certified sites

revealed substantial heterogeneity in infrastructure, staffing, procedure volumes (please refer to the next paragraph for details). These variations, and their potential impact on the consistency of clinical care, strongly justified a more advanced certification layer for centres operating at higher procedural complexity.

### 2. Level 1 enrolment and analysis

The EARL Theranostics Certification programme was launched on 1 July 2024. After one year (until 30 June 2025), 112 centres from 33 countries worldwide had enrolled and successfully obtained certification (Fig. 1).

To obtain certification, centres completed an enrolment form of more than 100 items, focusing on:

- clinical workload and diversity of treated indications,
- available instrumentation (PET/CT, SPECT/CT, radionuclide calibrators, radiopharmacy resources),
- interdisciplinary staffing levels,
- documentation practices in radiation protection, quality assurance, and regulatory compliance, and
- overall infrastructure readiness for expanding theranostic portfolios.

The analysis of these items identified several trends. First, there was a high variability in annual treatment volumes. Centres ranged from small units administering a few dozen therapies per year to high-capacity programmes delivering several hundred (range 11–1718). Notably, 72/112 centres (64%), across 24 countries, reported ≥250 administered therapies per year when considering all treatment types.

Second, the analysis revealed uneven access to hybrid imaging. While PET/CT or PET/MRI is essential for many theranostic pathways, a small number of Level 1 centres (N = 6) relied entirely on external imaging partners. Similarly, N = 7 centres reported no access to SPECT/CT.

Third, we observed significant disparities in staffing levels and staffing structure, highlighting a general shortage of personnel. Centres reported a median of 1 nuclear medicine physician per 50 administered therapies (range 2–311; Fig. 2A) and 1 medical physicist per 138 administered therapies (range 6–1324; Fig. 2B). Note that the median values would be higher when considering only the proportion of staff time devoted to theranostics, since no adjustment was made for time spent on other duties.

Additionally, some centres reported only on a single indication and consequently the use of only one radiopharmaceutical. Although

<https://doi.org/10.1016/j.eanmi.2025.100023>

Available online 24 December 2025

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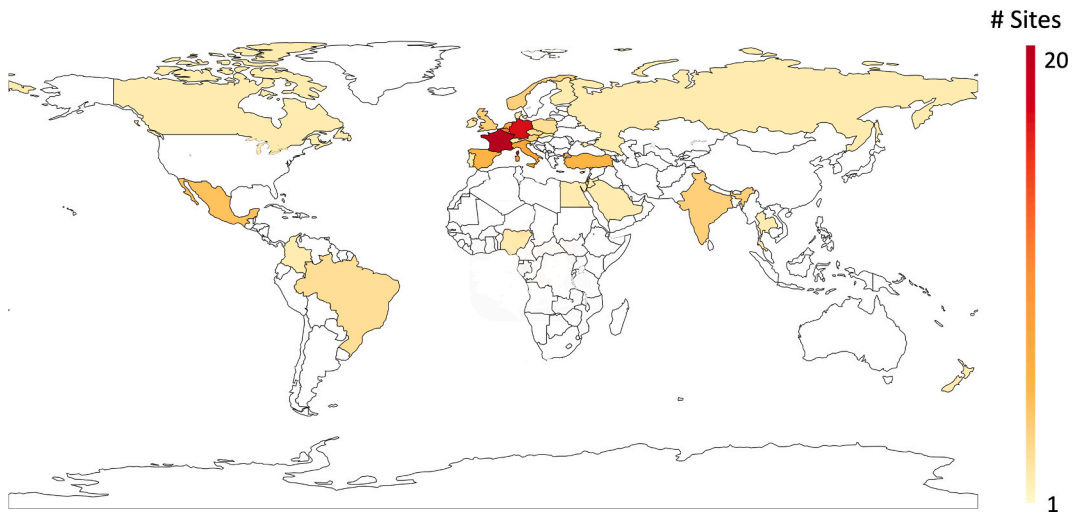


Fig. 1. Geographical distribution of the 112 certified centres. The largest number of qualified centres was located in France (N = 19, 17 % of the total), and 77 % of all enrolled sites were based in Europe.

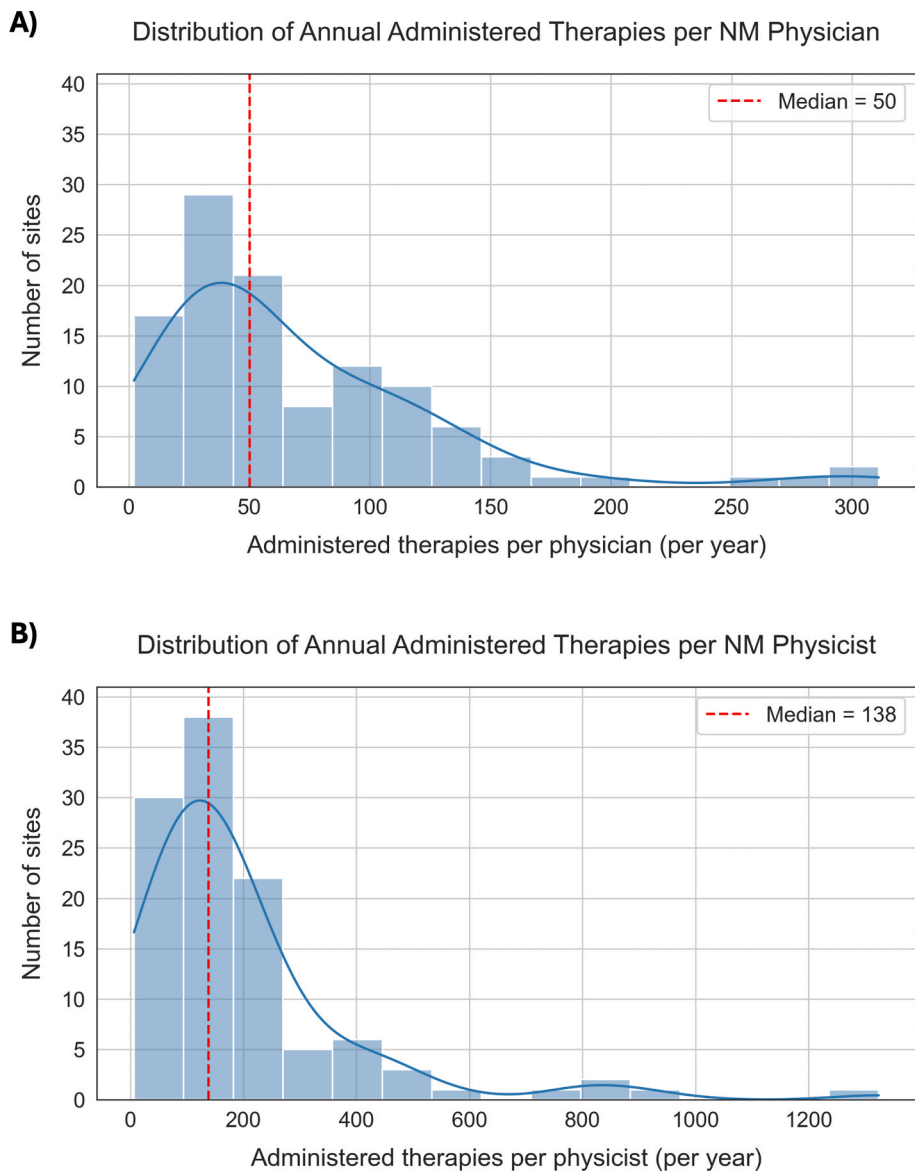


Fig. 2. Total number of administrations per nuclear medicine physician (A) and per nuclear medicine physicist (B) per year.

clinically valid, such a model represents a different level of expertise compared with centres routinely managing multiple tumour types and radiopharmaceuticals.

### 3. Rationale for level 2 certification

Overall, Level 1 succeeded in establishing a baseline quality framework, but as anticipated in foresight, it became clear that a differentiated structure was needed to recognise and promote centres with advanced capabilities and to provide clear guidance for centres striving toward higher standards. The new *Level 2 Advanced Theranostics Centre of Excellence* was therefore developed to identify institutions demonstrating readiness for complex, high-quality, and multi-indication theranostic practice. Level 2 requirements directly reflect the patterns observed in the Level 1 analysis and the elements most strongly associated with consistent, high-quality care. These include:

1. Diversity of clinical portfolio: Level 2 centres must routinely treat at least two different conditions using at least two different radiopharmaceuticals and radionuclides.
2. Strengthened staffing requirements: Level 2 centres should have at least 1 certified nuclear medicine physician and evidence of structured continuing professional development.
3. Infrastructure supporting advanced practice: Level 2 centres should have SPECT/CT available on-site, while for PET/CT or PET/MRI, formalised agreements with collaborating institutions are acceptable. At least one radionuclide calibrator must be available on site for accurate activity quantification. Level 2 centres must also hold a valid EARL PET/CT [<sup>18</sup>F] Standard 1 or 2 accreditation at the time of application.
4. Level 2 centres should guarantee adequate treatment volumes with enough procedures to develop and maintain high-level TRT expertise (target of 250 administered therapies/year based on current L1 data to include >60 % L1 sites or advanced experience in supporting research in nuclear medicine).

Together, these requirements define centres capable not only of safe practice but also of contributing meaningfully to research, education, and harmonisation efforts across Europe and beyond.

The introduction of Level 2 is not intended to create barriers but to provide a pathway toward maturity for evolving TRT programmes. Level 1, Level 2, and the forthcoming Level 3 (Educational/Research Centres) together form a progressive living framework:

- **Level 1** recognises centres meeting essential quality and safety requirements.
- **Level 2** identifies high-capacity centres with advanced infrastructure, diverse clinical activity, and sustainable, multidisciplinary expertise.
- **Level 3** (in development) will target centres capable of providing structured training, multicentre research environments, and leadership in emerging theranostic methodologies.

This tiered system strengthens the credibility of the field, supports regulators and industry partners, and provides patients with transparency regarding the maturity of services offered by different institutions.

We encourage institutions across Europe and beyond to consider the EARL Theranostics CoE Certification as both a quality benchmark and an opportunity for structured professional growth within this rapidly evolving field.

### Declaration of competing interest

Given their role as Editorial Board members of *EANM Innovation*, Caroline Stokke and Matteo Bauckneht had no involvement in the peer-review of this article and has no access to information regarding its peer-review. Full responsibility for the editorial process for this article was delegated to another journal editor.

All other authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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