EU POLICY & PROJECTS

Shaping the **future** of Nuclear Medicine in Europe **together**

FROM POLICY TO PATIENTS: BUILDING READINESS FOR NUCLEAR MEDICINE INNOVATION IN EUROPE

EU Policy Symposium 1 – Policy & Regulatory Affairs Council

EANM'25 Congress - Barcelona

Chairs:

Prof. Paola Anna Erba,

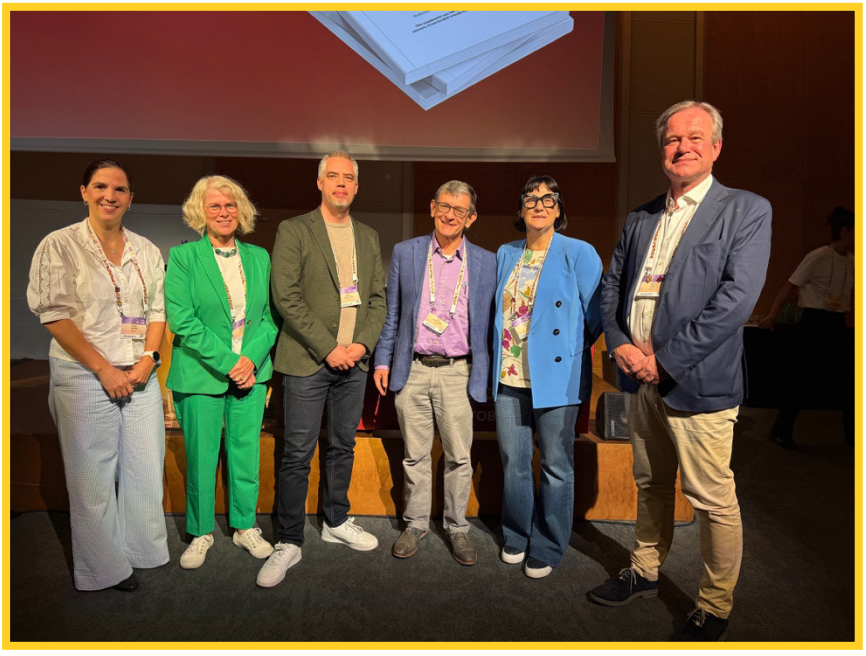
Prof. Wim Oyen

ABOUT THIS REPORT

This report summarises the discussions and key insights of the **EU Policy Symposium 1** at **EANM'25**:

From Policy to Patients: Building Readiness for Nuclear Medicine Innovation in Europe

Organised by the **EANM Policy and Regulatory Affairs Council**, the symposium brought together researchers, policymakers, RLT experts and clinicians to discuss the SIMPLERAD study policy recommendations, their upcoming implementation across Member States through the PRISMA Joint Action, projected trends in patient eligibility for radioligand therapies and their implications for healthcare planning including current challenges and opportunities in patient referral pathways.



Left to right:
Karolien Goffin, Anne-Laure Giraudet, Sampsa Kaijaluoto, Uwe Holzwarth, Paola Anna Erba, Wim Oyen

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EXECUTIVE SUMMARY

Europe stands at a pivotal moment in the development of radioligand therapies (RLT). While research and innovation in the field are advancing rapidly, health systems must now focus on practical readiness. This symposium examined the regulatory recommendations, projected trends in patient eligibility for RLT and current challenges and opportunities in patient referral pathways.

SIMPLERAD legacy and PRISMA

SIMPLERAD produced a **harmonised basis for regulation** of RLT in Europe. Building on this foundation, PRISMA, an 18-month Joint Action under the SAMIRA and Europe's Beating Cancer Plan frameworks, aims to **translate policy into coordinated national action.** Its core workstreams focus on RLT optimisation through national stakeholder groups, capacity building in nuclear medicine and the advancement of dosimetry standards.

Projected demand and uncertainties

Projections suggest that patients becoming eligible for new RLTs increase the number of patients seeking cancer treatment in nuclear medicine from currently around 100.00 to **up to 300,000 per year across Europe by 2035**. This would mean a dramatically **increased demand of roughly three times more for nuclear medicine.** However, significant uncertainties remain around reimbursement pathways, treatment guidelines and clinical trial data, which will influence adoption and access.

Main barriers and priorities

Six readiness areas were highlighted: improving referral pathways and imaging access; expanding workforce training; investment in specialised infrastructure; securing reliable radioisotope supply; aligning financial and regulatory frameworks; and strengthening standardisation in patient selection and dosimetry.

Access and next steps

While Europe now has the regulatory and data foundation in place, the **next phase requires coordinated national implementation, strategic investment and sustained collaboration** among regulators, professional societies, industry and patient groups **to ensure that every eligible patient can benefit from nuclear medicine innovation, wherever they live**.

SIMPLERAD MEETS PRISMA: FROM RECOMMENDATIONS TO IMPLEMENTATION

SIMPLERAD Legacy: Regulatory Lessons

Key recommendations and regulatory insights from the study

Prof. Dr. rer. nat Michael Laßmann, University of Würzburg - remote

The SIMPLERAD project was a study on the **implementation of the Euratom and EU legal bases with respect to the therapeutic uses of radiopharmaceuticals** under the **SAMIRA action plan**. Its main objectives were to clarify the interplay between European pharmaceutical and Euratom radiation regulations, identify implementation barriers, provide practical guidance and ensure quality and safety in the clinical use of therapeutic radiopharmaceuticals.

Key steps included analysing the links between EU pharmaceutical legislation and the Euratom Basic Safety Standards Directive (BSSD), surveying the implementation of legal requirements, conducting a project workshop and stakeholder consultation and developing actions to promote coherent implementation.

The survey revealed misalignment between pharmaceutical legislation and the BSSD on radiopharmaceuticals, causing interpretation and procedural inconsistencies across Europe; proposed actions include more resources, closer stakeholder collaboration, specialist training and joint regulatory guidance.

The **final report** was **published** in 2025 including two guidance documents (Annex I: Visions on Dosimetry in Clinical Practice, Annex II: Guidance Document on Treatment Planning and Verification for Selected Radiopharmaceuticals). It also endorsed the EANM Guidance Document on Dosimetry for First-In-Human Studies and Early Phase Clinical Trials.

Some Priority issues are being addressed as a Legacy of SIMPLERAD:

- **Disconnection between marketing authorisation of radiopharmaceuticals and the BSSD:**
- European Medicines Agency (EMA) is currently developing a guideline on clinical evaluation of therapeutic radiopharmaceuticals in oncology. The scope of this future guideline is to provide specific guidance on how the key concepts from the two areas of legislation should be applied to the clinical development of therapeutic radiopharmaceuticals for marketing authorisation application. The EANM has been involved in the development of this guideline through contributing feedback to the initial concept paper and future participation to the follow up workshop in 2026.

- **Differences in interpreting and implementing the BSSD in the context of therapeutic nuclear medicine:**
  - A pending plan from the European Commission (DG SANTE) to establish a dedicated Working Group on radiotheranostics aiming at following developments related to cross-policy guidance (BSSD and Clinical Trials Regulation) could also support finding a consensus on the potential inclusion of dosimetry in clinical trials.
- **Lack of resources for dosimetry:**
  - EANM and the European Federation of Organisations for Medical Physics (EFOMP) set up a dedicated Working Group to revise the core curriculum. The update is currently under review.
- **Heterogeneity of Dose Constraints and patient-release Criteria between Member States:**
  - Project group on patient release criteria formed by EANM (in collaboration with EURADOS and HERCA)
  - HERCA Workgroup Medical Applications preparing a guidance paper on Dose Constraints in therapeutic Nuclear Medicine for carers and comforters and members of the public

CARRYING THE TORCH: PRISMA VISION

How PRISMA is Translating Recommendations into Policy and Practice.

Senior inspector Sampsa Kaijaluoto, Finnish Radiation and Nuclear Safety Authority

PriSMA (Preparatory Activities to Support Implementation of Quality and Safety of Medical Ionising Radiation Applications) was introduced in May 2024 as a tool to **improve radiation quality and safety in medicine** (one of SAMIRA Action Plan's priorities within the context of **Europe's Beating Cancer Plan**). By establishing the necessary frameworks and methodologies, PriSMA is laying the groundwork for the direct implementation of the SAMIRA Joint Action, scheduled to commence in 2026.

Joint Actions (JA) are defined as a **cooperation between authorities** with Competent Authority (CA), Affiliated Entity (AE) and Associated Partner (AP) participating.

The key objectives of PriSMA are:

1. To **map the relevant actors** in Member States and conduct network activities to promote future initiatives
2. To jointly **produce a proposal for a future Joint Action** in the area of quality and safety of medical applications of ionising radiation, including objectives, scope and activities.

12 projects were proposed by PriSMA for future JA. **'Optimization of Radionuclide Therapy'** was highlighted among them with its objectives defined as to implement Euratom 2013/59 dosimetry requirements in radiopharmaceutical therapy and ensure coordinated communication between regulators and stakeholders for coherent application, including treatment optimisation and patient-release criteria.

» The proposed project plans to establish working groups in each Member State comprising key national stakeholders, including medicines agencies, radiation protection authorities, HTA bodies and professional representatives, to tackle the priority remedies identified in the SIMPLERAD report. Most work will be conducted within these national groups, complemented by periodic EU-wide workshops where stakeholders can exchange experiences, discuss challenges, and share best practices to support coherent implementation across Europe.

There is a **clear political commitment** to act next year with **funding available through EU4Health. EU4Health 2025 Work Programme** defines SAMIRA JA on pages 43-45 and outlines the implementation budget of 11 500 000 EUR.

Future SAMIRA Joint Action Objectives are to improve quality and safety of medical radiology, apply SAMIRA lessons and recommendations across multiple countries and provide a forum for exchanging best practices between Member States. The mandatory deliverables will include six main actions, among them the **implementation of the requirements of Council Directive 2013/59/ Euratom Basic Safety Standards Directive related to optimisation and dosimetry in radiopharmaceutical cancer therapy.**

FROM POLICY TO CLINICAL PRACTICE: CAN SYSTEMS KEEP UP WITH THE PACE OF INNOVATION?

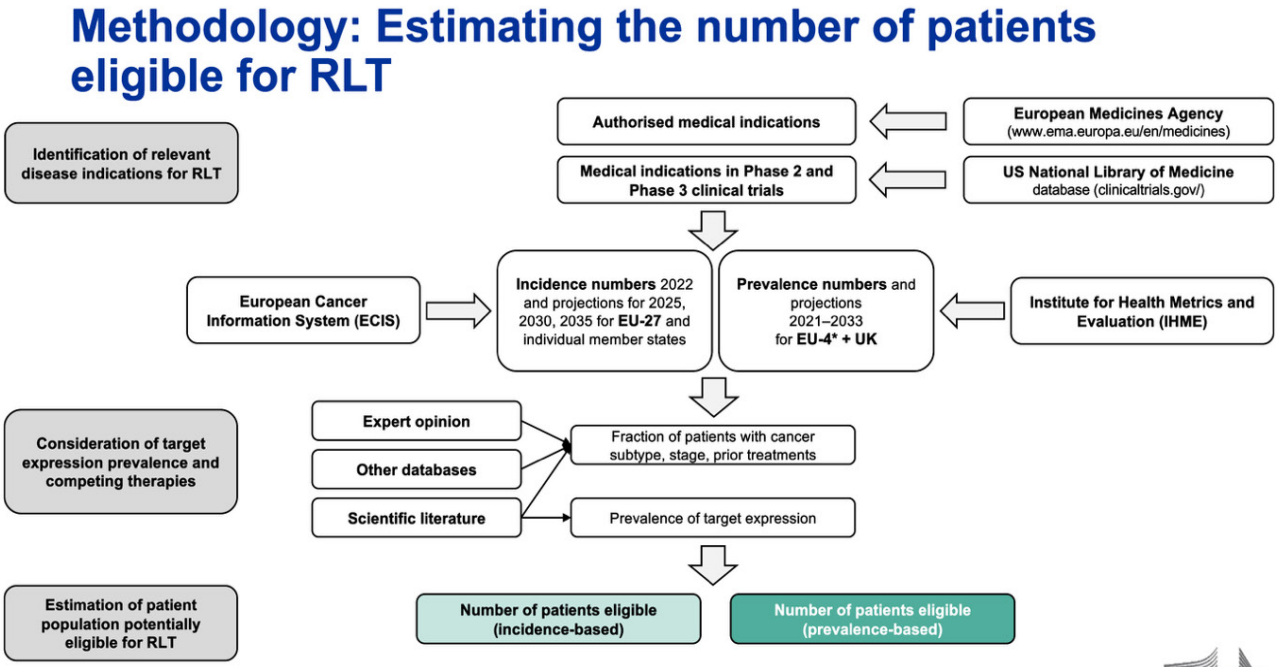
Anticipating the Wave: How Many Patients, How Soon?

Forecasting the number of eligible patients and expected growth.

PHD (Dr. rer. nat.) Uwe Holzwarth, Joint Research Centre - European Commission, Ispra

The session focused on the results of a study conducted by European Commission's Joint Research Centre in collaboration with RLT Healthcare Systems Readiness & Partnerships (Novartis), WifOR – Macroeconomic Research Institute & Think Tank, Department of Health Policy, London School of Economics and Political Science and University Hospital Tübingen.

The analysis included identifying ongoing clinical trials using approved radiopharmaceuticals (RFs) and evaluating how expanding medical indications and the development of new RLT procedures could increase the number of cancer patients treated in nuclear medicine.



EU-4 includes France, Germany, Italy and Spain.
ECIS, European Cancer Information System; IHME, Institute for Health Metrics and Evaluation; RLT, radioligand therapy.

The results clearly show that expanding medical indications and the emerging RLT products may **dramatically increase the number of cancer patients in nuclear medicine by the year 2035** on top of the already existing workload.

The following **uncertainties** were listed in the context of the findings: national specificities (reimbursement decisions , treatment guidelines), additional considerations (alternative treatments, development and trial-related risks), actual number of patients (131I therapy for thyroid cancer, 131I therapy for benign thyroid disorders, radioembolisation of liver lesions , other less frequent therapies).

The conclusions indicate that by 2035, approximately **70% of radioligand therapy patients** across the EU-27 are **expected to be treated with ^{177}Lu-based compounds, resulting in an additional annual demand of around 3,000 to 4,300 TBq of ^{177}Lu.** At the same time, the **α-emitter ^{225}Ac is expected to become increasingly significant,** particularly for the estimated 35% of patients who show limited or no response to β-emitter therapies. **Parallel growth is expected in the use of ^{68}Ga-based imaging,** reflecting the rising number of **patients eligible for theranostic approaches.**

Meeting these future needs will depend on much more than isotope production and availability. It will require sustained investment in a **highly skilled, multidisciplinary workforce** including nuclear medicine and oncology specialists, medical physicists, nurses, radiopharmacists, and radiation protection professionals.

Equally important will be the **expansion and licensing of clinical facilities with adequate capacity** for imaging, dosimetry, and therapeutic administration. **Strengthening this capability will be vital to support the growing use of radioligand therapy across Europe**, ensuring treatments are delivered safely, effectively, and to a consistent standard. This will ultimately lead to **better care and better outcomes for patients.**

GROWING THE CAPACITY OF HEALTHCARE SYSTEMS FOR RADIOLIGAND THERAPY

Addressing Main Barriers and Challenges.

Prof. Dr. Karolien Goffin, KU Leuven, Belgium

With a growing pipeline, RLT is moving from a niche therapy to a central element of multimodal oncology, highlighting the need for substantial systemic investment. Current healthcare systems are not equipped to meet this rising demand, leading to delays and inequitable patient access.

Challenge I: Diagnostic Capacity and Patient Referral

Limited access to diagnostic tools, such as PET scanners, and low uptake—only 15–20% of eligible mCRPC patients receive a PSMA test in some European countries—hinder patient identification. Fragmented workflows and the lack of standardised referral pathways further delay care. Solutions include investment in equipment, improved reimbursement, clear patient pathways, integration into national cancer plans, and capacity surveys to optimise resources.

Challenge II: Shortage of Specialist Workforce

Trained RLT personnel are scarce, with one nuclear medicine physician per 50 administrations and one physicist per 138. Barriers include long training pipelines, limited RLT exposure, and regional disparities. Solutions include accelerated, flexible training, advanced certification for nurses, physicists, and technologists, and targeted policy support.

Challenge III: Infrastructure and Capital Investment

RLT requires specialised infrastructure, strict compliance, and adequate radioactive waste management. Solutions include financial support for radioprotection and waste disposal, modular construction to reduce downtime, and investment in centralised, automated production facilities.

Challenge IV: Radioisotope Supply Chain Vulnerability

Critical radioisotopes, such as Lu–177 and Ac–225, are limited and require rapid 'just-in-time' delivery. Strengthening supply chains requires international policy coordination and investment in globally distributed, automated production facilities.

Challenge V: Financial and Regulatory Integration

Inconsistent regulatory frameworks, fee-for-service models, and high patient co-payments restrict access and multidisciplinary care. Solutions include bundled payments covering the full RLT episode and aligned incentives to support coordinated delivery.

Challenge VI: Standardisation and Harmonisation

Fragmentation across the RLT process calls for standardisation in patient selection, imaging, treatment, post-therapy imaging, dosimetry, and system calibration to ensure consistent, safe, and effective care.

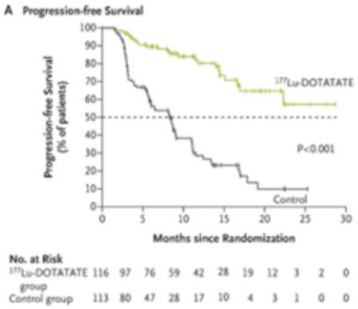
RIGHT PATIENT, RIGHT TIME: STREAMLINING ACCESS TO INNOVATION

Highlighting Urgent Bottlenecks and Opportunities in Patient Access and Referral.

Dr. Anne-Laure Giraudet, Centre Léon Bérard, Lyon

RLT, particularly PSMA-based treatment for prostate cancer, is transforming the landscape of targeted cancer care. However, many patients still face significant barriers to timely access, preventing them from receiving treatment when it is most effective. Evidence shows that outcomes are markedly improved when RLT is delivered earlier in the disease course – with better survival, improved PSA responses, and enhanced quality of life. Delays in access can therefore mean lost opportunities for patients.

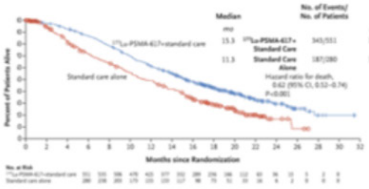
Progression-Free Survival



Control the growth of the disease

Strosberg et al., N Engl J Med 2017

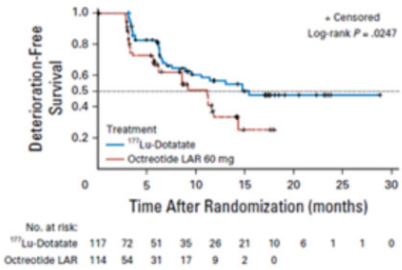
Overall Survival



Make patient live longer

Sartor et al., N Engl J Med 2021

Quality of life: e.g. pain



Make patient live better

Strosberg et al., J Clin Oncol 2018

Key Bottlenecks

1. Infrastructure and Capacity Constraints

- Shortages in radiopharmaceutical supply and a limited number of treatment centres.
- Insufficient workforce capacity within nuclear medicine and patient navigation.
- Marked disparities in access between urban and rural areas, and across socioeconomic groups.
- A 2024 French survey found that only around **2,240 of 5,700 eligible patients** were able to receive RLT due to limited capacity.
- As a result, many eligible patients are never discussed at multidisciplinary meetings or referred for treatment.

2. Specialist Knowledge Gaps

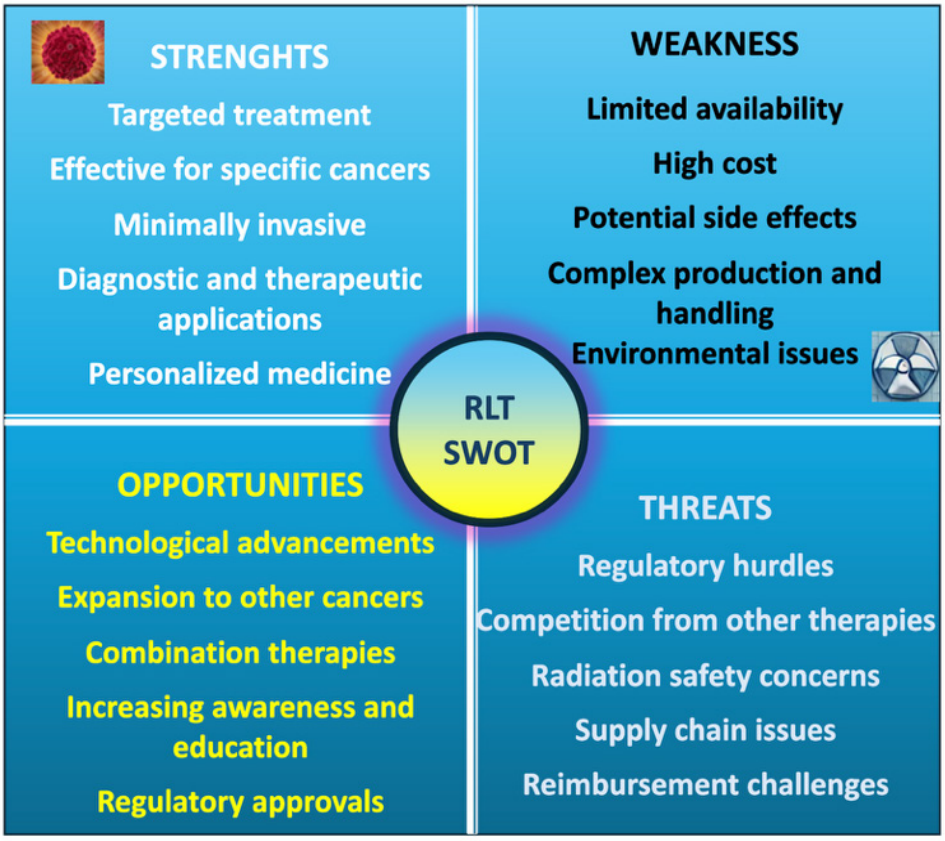
- Many oncologists and general practitioners remain unaware of RLT or its potential indications.
- RLT is not yet fully integrated into standard clinical guidelines.
- Fragmented systems and a lack of coordination between oncology, radiology, and nuclear medicine services hinder referrals.
- Greater **multidisciplinary collaboration,** improved communication, and expanded training are essential to increase awareness and reduce uncertainty.

3. Regulatory and Reimbursement Barriers

- Complex administrative processes, lengthy approval times, and inconsistent regulatory frameworks across Europe.
- Reimbursement often lags behind clinical approval.
- Legal and safety requirements further complicate access.
- Initiatives such as the **JANE programme** aim to promote harmonisation and more efficient reimbursement systems across the EU.

4. Radioprotection and Environmental Issues

- Significant variation exists between countries in terms of patient release criteria and the management of radioactive waste.
  - For example, isolation times vary from three days in Germany to 20 hours in Switzerland.
- These differences limit treatment capacity and flexibility.
- There is a clear opportunity for **EU-wide harmonisation** of radioprotection standards, enabling safer outpatient care and expanded access.



Europe is well placed to lead the way in equitable RLT access. Initiatives such as PRISMAP are securing European isotope production, while the EANM and European authorities are working together to develop unified guidelines and educational programmes. The next step is for **each member state to organise national strategies** that ensure fair access, foster multidisciplinary collaboration, and build an interconnected ecosystem linking oncologists, nuclear medicine specialists, regulators and policymakers.

KEY POLICY RECOMMENDATIONS

The symposium underscored the growing importance of Radioligand Therapy (RLT) in advancing cancer care across Europe. Participants agreed that achieving equitable access will require coordinated efforts to clarify clinical pathways, support new infrastructure and facilitate workforce development.

Most notable **policy action points** are:

1. Referral Pathways:

Referral pathways for RLT should be clearly defined within national cancer plans with standardised eligibility criteria, digital referral tools and guideline updates. This is a clear opportunity for professional societies (including EANM) to develop the frameworks.

2. Infrastructure, Capacity and Supply Chain Resilience:

The EU should invest in and further expand initiatives such as **PRISMAP** or **ERVI** (European Radioisotope Valley Initiative) which contribute to strategic autonomy and supply resilience and also prepare the continent for the expected increased demand for RLT.

3. Workforce Development and Education:

The EU should support more projects that would facilitate access in Member States to high quality education for nuclear medicine specialists, radiochemists, physicists and technologists such as the **RLT Academy** that was developed through the Erasmus+ funding stream.

4. Regulatory Alignment and Evidence Strengthening:

Support should be given to researchers to prioritize the collection of real-world data collection that accurately reflects clinical practice. This would enable regulatory frameworks such as HTA (Health Technology Assessment) to evaluate innovations more efficiently, allowing patients to benefit soon from the real-life application of the technologies such as RLT sooner (as analysed in more detail in the EANM'25 Policy Symposium 2.)

5. Harmonisation and Standardisation:

Centres that demonstrate high standards of safety and consistency should be recognised through accreditation and certification programs, such as the **EARL** Theranostics Centres of Excellence network. Such recognitions can serve as a motivational incentive for other centres across the EU to invest in meeting the programs' criteria, thereby raising overall standards of patient care and achieving more procedural homogeneity.

6. Research, Innovation and Collaboration:

EU authorities should prioritize and strengthen support for multinational research initiatives and actively encourage the development of academic sponsored trials. Initiatives such as ACT EU (Accelerating Clinical Trials in Europe) are fostering academic collaboration and strengthening Europe's competitiveness in clinical research. Increased commitment to such efforts would enhance Europe's research capacity, accelerate innovation and secure a stronger competitive position in theranostics and precision oncology.

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European Association of Nuclear Medicine

Schmalzhofgasse 26,
1060 Vienna, Austria

+43 1 890 44 27

office@eanm.org

www.eanm.org

EDITORS

EANM Executive Office

Amélie de Martini
Daria Ferrara
Mirka Kurčíková
Moritz Zieglmeier

LAYOUT & DESIGN

EANM Executive Office

Olga Dogadina

CONTENT

While every effort has been made to ensure accuracy, the EANM Executive Office cannot assume responsibility for any inadvertent errors or omissions.

CONTACT

EUaffairs@eanm.org