

WORKING PAPER

Clinical Trials in Nuclear Medicine: Towards a More Enabling Framework

Key message: Unlocking the potential of nuclear medicine clinical trials requires a shift towards proportionate regulation, stronger European coordination and sustainable research capacity. The proposed actions are a starting point for collective action, with partners invited to support or lead individual deliverables.



BACKGROUND

Nuclear medicine represents a good example of precision medicine, because it sits at the **intersection of molecular imaging and targeted therapy**, thus allowing disease to be biologically characterised, precisely treated and accurately monitored according to individual patients.

Read more on Nuclear Medicine in our paper [Nuclear Medicine: What it is. Where it goes. What it needs.](#)

Clinical trials in nuclear medicine span **diagnostic, therapeutic and integrated theranostic applications**, with substantially **different levels of prior clinical experience, uncertainty and additional risk**. Regulatory requirements should therefore be proportionate to the characteristics of the investigational radiopharmaceutical and trial procedures, including prior clinical experience, known or anticipated adverse events, pharmacological and radiation exposure, dosimetry, and procedural complexity, rather than being determined primarily by classification as diagnostic or therapeutic.

DEFINITIONS

For the purposes of this document, three broad settings should be distinguished: **(1) diagnostic radiopharmaceuticals used for molecular imaging; (2) imaging radiopharmaceuticals used as biomarkers for patient selection, treatment eligibility or response assessment within trials of radiopharmaceutical or non-radiopharmaceutical therapies; and (3) therapeutic radiopharmaceuticals**. These settings differ substantially in their intended use, prior clinical experience, pharmacological and radiation risks, and regulatory requirements. The recommendations for regulatory simplification and risk-proportionate approaches presented in this document apply primarily to diagnostic and imaging applications. Therapeutic radiopharmaceutical trials require specific assessment according to their pharmacological, radiation and procedural risks and should not be assumed a priori to qualify for a minimal- or low-intervention approach.

The **minimal-intervention** clinical trial (MICT) and **low-intervention** clinical trial (LICT) concepts are especially important here, as recently discussed within the first part of the [European Biotech Act](#).

Get familiar with EANM's position through the dedicated [Policy Brief on the Biotech Act](#).

The MICT and LICT concepts are particularly relevant to nuclear medicine when the investigational component involves diagnostic imaging with authorised or well-characterised radiopharmaceuticals and introduces only limited additional risk or burden compared with established clinical practice. **The use of a radiopharmaceutical should not, by itself, preclude consideration of a proportionate**

regulatory approach, provided that the applicable conditions are fulfilled. Such assessment should take into account prior clinical experience, the safety profile of the radiopharmaceutical, administered activity and radiation exposure, patient population, additional trial procedures and overall procedural complexity. **Particular consideration may be required for diagnostic agents associated with higher radiation exposure, including certain longer-lived radionuclides, and for vulnerable populations.**

For the purposes of this document, **academic/non-commercial sponsors** are organisations, including universities, research institutions and public-sector bodies, that initiate, support or conduct clinical research without a primary commercial interest in the development, registration or marketing of a medicinal product. These organisations are referred to as “sponsors” throughout the document.

AIM

The [European Association of Nuclear Medicine](#) conducted a **community-wide survey** in late 2025 to identify the key pain points as a first step towards addressing them. The results are available in the publication here. These **findings provide the structure for the following recommendations** on how to create a more supportive and enabling environment for nuclear medicine clinical trials in the short- medium- and long-run.

Read the publication [Regulatory and Organisational Barriers to Non-Commercial Clinical Trials in European Nuclear Medicine: Results from an EANM Survey](#).

This document aims to provide a **foundation for consensus and collective action** within the community. It is intended as a **living framework that can evolve** through continued dialogue, collaboration and exchange, and welcomes the perspectives and contributions of our community, partners and other relevant stakeholders. Find the recommendations below grouped into the following chapters:

1. REGULATORY SIMPLIFICATION AND HARMONISATION
2. EARLY AND CONTINUOUS REGULATORY SUPPORT
3. INFRASTRUCTURE AND ACCESS TO RADIOPHARMACEUTICALS
4. WORKFORCE CONSTRAINTS AND ROLE RECOGNITION
5. COORDINATION, EQUITY, COLLABORATION AND FUNDING
6. CLINICAL TRIAL DESIGN AND METHODOLOGICAL SUPPORT
7. PATIENT ENGAGEMENT AND ACCESS TO CLINICAL TRIALS

1. REGULATORY SIMPLIFICATION AND HARMONISATION

1.1. Short-term actions

1.1.1.

Develop practical EU guidance on MICT/LICT classification for nuclear medicine

trials: Develop a short EU-level guidance or Q&A document with practical examples to clarify when nuclear medicine trials using authorised or well-characterised radiopharmaceuticals, may qualify as minimal- or low-intervention clinical trials. Examples should cover diagnostic PET and SPECT, imaging-only studies, dosimetry studies, paediatric imaging studies, and diagnostic imaging procedures performed within therapeutic development programmes, while clearly distinguishing these from trials investigating the therapeutic radiopharmaceutical itself.

Deliverable: EU Q&A/guidance with practical examples

Stakeholders: EANM (ACT EU Project Group)

1.1.2.

Clarify requirements for imaging biomarkers embedded in therapeutic trials:

Develop practical guidance for imaging radiopharmaceuticals used for patient selection, treatment eligibility, target-expression assessment or response evaluation within therapeutic clinical trials. Regulatory requirements for the imaging component should be proportionate to its intended role in the trial and should avoid unnecessary duplication of diagnostic-effectiveness requirements when the imaging procedure is not being independently developed for a diagnostic indication.

Deliverable: EU guidance on the regulatory assessment of imaging biomarkers embedded in therapeutic clinical trials

1.1.3.

Promote consistent application of proportionate requirements for MICT/LICT:

Develop practical recommendations (i.e., checklists), common templates and examples to promote greater consistency in the application of requirements for documentation, monitoring, safety reporting, quality management and insurance once a trial has been classified as MICT/LICT, that would be beneficial across Member States.

Deliverables: MICT/LICT toolkit with checklists and common templates

1.1.4.

Improve CTIS support for nuclear medicine trials: Develop nuclear medicine-specific guidance, examples and practical support for sponsors using CTIS, particularly academic/non-commercial sponsors, to reduce avoidable administrative complexity and improve consistency in submissions.

Deliverables: Nuclear medicine-specific CTIS guidance, model submission pathway and practical examples for academic/non-commercial sponsors

Stakeholder: EANM (ACT EU Project Group)

1.1.5.

Reduce unnecessary reporting for eligible radiopharmaceutical trials: For diagnostic and imaging-biomarker trials using authorised or well-characterised radiopharmaceuticals, safety reporting should be proportionate to the established safety profile, radiation exposure and additional risks introduced by the trial. Practical guidance should clarify how existing safety-reporting requirements can be applied proportionately, avoiding unnecessary duplication or reporting of well-characterised events, while remaining fully aligned with applicable regulatory requirements.

Deliverable: Risk-based safety-reporting algorithm/guidance for authorised or well-characterised radiopharmaceuticals

1.2. Medium-term actions

1.2.1.

Strengthen mutual reliance within existing regulatory processes: Develop a common core radiopharmaceutical dossier and promote greater reliance on the reporting Member State's substantive Part I assessment in multinational clinical trials, while preserving scope for justified national considerations. The core dossier should be reusable across trials and centres, with only site-specific manufacturing or handling information added locally. A similar non-binding approach could also be explored for GMP inspections and quality assessments.

Deliverable: Common core radiopharmaceutical dossier and recommendations for greater reliance on Part I assessments

1.2.2.

Improve digital standardisation of trial documentation: Promote structured and reusable regulatory information within CTIS, including common radiopharmaceutical documentation and templates, to reduce duplication across multinational trials.

Deliverable: Standardised/reusable CTIS templates

1.3. Long-term actions

1.3.1.

Further harmonise the EU approach to risk-based classification: Experience gained from the implementation of MICT/LICT criteria could inform a more harmonised EU approach to risk-based classification, with clearer and consistently applied criteria for diagnostic trials.

Deliverable: European analysis of classification practices and proposal for harmonised criteria.

1.3.2.

Consider further alignment of regulatory requirements: Where significant differences between Member States persist despite guidance, coordination and mutual reliance, further alignment of regulatory requirements should be considered, including through future legislation or policy.

Deliverable: Gap analysis identifying persistent national differences and recommendations for further regulatory alignment

2. EARLY AND CONTINUOUS REGULATORY SUPPORT

2.1. Short-term actions

2.1.1.

Provide early regulatory guidance: Investigators and academic/non-commercial sponsors should have access to regulatory advice from the earliest stages of trial development, including advice on MICT/LICT classification, investigational product, trial design, imaging/dosimetry, safety monitoring and radiation protection.

Deliverable: Early-advice pathway covering MICT/LICT classification

2.2. Medium-term actions

2.2.1.

Strengthen continuous regulatory dialogue: Establish structured interaction between investigators, academic/non-commercial sponsors, regulators and technical experts throughout trial development to identify and address regulatory and methodological issues early

Deliverable: European Nuclear Medicine Regulatory Forum with regular interaction between regulators, investigators, academic/non-commercial sponsors and experts

2.3. Long-term actions

2.3.1.

Harmonise technical methodologies: Long-term regulatory dialogue should support consistent European regulatory approaches to imaging, dosimetry and radiation-risk assessment, while technical and methodological standards, particularly for quantitative imaging and dosimetry, should primarily be developed by the scientific community in dialogue with regulators. Such collaboration would help reduce methodological variability and improve comparability across clinical trials

Deliverable: European recommendations on imaging acquisition, quantitative imaging

3. INFRASTRUCTURE AND ACCESS TO RADIOPHARMACEUTICALS

3.1. Short-term actions

3.1.1.

Facilitate access through collaboration and shared infrastructure: Inter-institutional collaboration and networking could help address limited access to PET/SPECT scanners, specialised radiopharmaceuticals, manufacturing capacity and dosimetry expertise, particularly for multicentre academic trials.

Stakeholders: EANM and the EANM National Delegates

3.1.2.

Strengthen European research networks and shared capacity.: Develop collaborative networks linking centres with complementary imaging, radiopharmaceutical production and dosimetry capabilities to facilitate access to specialised infrastructure and expertise for multicentre trials.

Deliverable: European map of infrastructure and expertise, identifying capabilities and gaps.

Stakeholder: EANM and the EANM National Delegates.

3.1.3.

Promote common imaging and dosimetry approaches: Implementation of existing harmonised imaging and quantitative methodologies could improve comparability and facilitate participation across centres. EANM/EARL standards provide an important foundation for technical harmonisation and quantification. However, multicentre clinical trials may require additional trial-specific standardisation, including acquisition timing, reconstruction and analysis procedures, quality control, dosimetry where applicable, and integration with CT/MRI. Efforts should therefore focus both on increasing awareness and implementation of existing standards and on defining trial-specific imaging requirements where needed.

Deliverables: Implementation package building on existing EANM/EARL standards, complemented by recommendations for trial-specific imaging standardisation in multicentre studies.

Stakeholder: EANM and other societies

3.2. Medium-term actions

3.2.1.

Facilitate cross-border access to radiopharmaceuticals: Explore practical mechanisms to facilitate access to radiopharmaceuticals and precursors across Member States, particularly for academic and investigator-initiated trials, while respecting national manufacturing, GMP and transport requirements.

Deliverable: Creation of a step-by-step producer-to-site pathway model referencing various release, transport, back-up supply and handling deviations.

Stakeholders: EANM and other societies

3.2.2.

Promote regional centres of expertise: Encourage the development of regional or national centres with specialised radiopharmaceutical production, imaging and dosimetry capabilities that can support surrounding institutions participating in clinical trials.

Deliverable: Networked model of regional/national centres supporting surrounding trial centres.

Stakeholder: EANM and other societies

3.3. Long-term actions

3.3.1.

Strengthen the European radiopharmaceutical supply chain: Long-term strategies should address structural challenges in the availability, manufacturing and distribution of novel radiopharmaceuticals and their precursors, supporting resilient supply and broader participation in clinical trials across Member States.

Deliverable: European radiopharmaceutical supply-chain risk map and strategy

Stakeholders: EMA, EANM and other societies

4. WORKFORCE CONSTRAINTS AND ROLE RECOGNITION

Useful publication: [EANM nuclear medicine workforce survey: Sentiments, gaps, and strategic priorities in Europe](#)

4.1. Short-term actions

4.1.1.

Make better use of the existing workforce: Nuclear medicine technologists, who represent a major part of the workforce, could be more actively involved in clinical research, with appropriate preparation and recognition of their expertise and opportunities to contribute to trial leadership.

Deliverable: Competency-based training programme for Nuclear Medicine Technologists involved in clinical research

Stakeholder: EANM/ESMIT

4.1.2.

Support research capacity: Funding for research-protected time and trial-specific staff would help reduce the impact of clinical workload on research engagement and strengthen centres' capacity to participate in trials.

Deliverable: Funding mechanisms supporting protected research time and trial-specific staff (i.e., dedicated PhD positions in nuclear medicine clinical trials)

4.2. Medium-term actions

4.2.1.

Strengthen professional roles and competencies: Develop clearer role descriptions and competency frameworks for nuclear medicine professionals involved in clinical research to support their participation in trial delivery and research activities.

Deliverable: European competency framework and role descriptions for professionals involved in clinical research

4.2.2.

Promote cross-border training and professional development: Support and fund shared training programmes, fellowships and continuing professional development opportunities to facilitate skills development, knowledge exchange and workforce mobility across Member States, by focalizing the attention on nuclear medicine.

Deliverable: European Nuclear Medicine Clinical Trials Training Programme, including fellowships, exchanges and mentoring developed through interinstitutional collaboration and funding

4.3. Long-term actions

4.3.1.

Develop a recognised European nuclear medicine curriculum and specialty: Longer-term consideration could be given to developing a more consistent, EU-recognised curriculum and training framework for nuclear medicine, alongside greater recognition of nuclear medicine as a specialist field. This could support harmonised competencies, strengthen workforce mobility and help ensure that centres across Europe have access to appropriately trained professionals able to contribute to clinical research and deliver increasingly complex diagnostic and therapeutic applications

Deliverable: European curriculum and harmonised training framework for nuclear medicine

5. COORDINATION, EQUITY, COLLABORATION AND FUNDING

5.1. Short-term actions

5.1.1.

Improve dissemination and coordination: Better dissemination of opportunities to participate in trials, including at the trial-design stage, could help broaden participation and address the concentration of studies in a limited number of countries and centres.

Deliverable: Optimising CTIS for better dissemination capabilities through targeted filtering and notifications

5.1.2.

Deepen European research partnerships: Greater collaboration between European academic networks and established research organisations, such as EORTC (i.e., methodological support, protocol development, quality assurance and the operationalisation of investigator-initiated concepts into multinational academic trials), could support broader participation, shared expertise and more efficient trial delivery.

Deliverable: Formal collaboration mechanism for identifying and developing multicentre nuclear medicine trials

5.1.3.

Strengthen funding and collaboration with industry: Dedicated funding should support investigator-led nuclear medicine trials, including multicentre coordination, research infrastructure, radiopharmaceutical access and protected research time. Academic–industry collaboration may provide investigational products, technologies, regulatory expertise and co-funding while preserving academic independence. Standardised nuclear medicine site agreements and cost templates, covering radiopharmaceutical production/purchase, quality control, transport, imaging/dosimetry, radiation protection and inpatient capacity where relevant, could reduce negotiation-related delays and accelerate site activation.

Deliverables: European funding and academic–industry collaboration framework, including a standard nuclear medicine site agreement and cost template

5.2. Medium-term actions

5.2.1.

Establish coordinated mechanisms for trial participation: Develop European mechanisms to facilitate the identification of centres, investigators and patients for multicentre nuclear medicine trials, with particular attention to countries and centres currently underrepresented in clinical research.

Deliverable: European mechanism connecting academic/non-commercial sponsors with qualified centres

5.2.2.

Develop sustainable funding and collaboration models: Promote funding models combining European, national, academic and industry resources to support multicentre investigator-led trials, shared infrastructure and trial coordination.

Deliverable: Co-funding model combining EU, national, academic and industry resources

5.2.3.

Strengthen cross-border collaboration and capacity building: Support mentoring, twinning and collaborative programmes between experienced and less-experienced centres to broaden expertise and enable wider participation in clinical trials.

Deliverables: Mentoring/twinning programme linking experienced and developing centres

5.3. Medium-term actions

5.3.1.

Coordinate clinical trial and radiation protection requirements: Greater coordination between the CTR and applicable Euratom and national radiation protection requirements would be beneficial, including through coordinated documentation, contact points and assessment timelines. This would maintain existing radiation protection standards while helping to reduce unnecessary procedural fragmentation.

Deliverable: Coordinated CTR/Euratom checklist, documentation and contact-point model

5.3.2.

Develop more coordinated European research and funding mechanisms: Longer-term European research programmes could provide more sustained support for

investigator-led multicentre trials, shared infrastructure and cross-border research networks, helping to broaden research capacity and participation across Member States.

Deliverable: Dedicated nuclear medicine priorities/mechanisms within European research programmes

5.3.3.

Encourage convergence in radiation-risk and dosimetry assessment: Common methodological principles for dosimetry, radiation-risk assessment, imaging requirements, patient-release criteria and reporting of radiation exposure could support more consistent assessments across Europe.

Deliverables: Common methodological principles

6. CLINICAL TRIAL DESIGN AND METHODOLOGICAL SUPPORT

6.1. Short-term actions

6.1.1.

Promote methodological support for nuclear medicine trials: Develop practical methodological resources covering trial design, endpoints, sample-size considerations, imaging biomarkers, dosimetry and statistical analysis to support robust and feasible nuclear medicine clinical trials, particularly for early-phase therapeutic trials. These methodological recommendations should address diagnostic and therapeutic trials separately, recognising their different objectives, endpoints, safety requirements and regulatory pathways.

Deliverable: Nuclear Medicine Clinical Trial Methodology Toolkit

Stakeholder: EANM (ACT EU Project Group)

6.2. Medium-term actions

6.2.1.

Develop common methodological recommendations: Promote European recommendations for the design and conduct of diagnostic, therapeutic trials, including appropriate endpoints, imaging response criteria and methodology, quantitative biomarkers and dosimetry.

Deliverable: European consensus recommendations for diagnostic and therapeutic trial design

6.3. Long-term actions

6.3.1.

Establish a European methodological framework for nuclear medicine trials: Develop a harmonised framework supporting innovative trial designs and the integration of imaging, biomarkers, dosimetry and therapeutic endpoints.

Deliverable: Harmonised European methodological framework

7. PATIENT ENGAGEMENT AND ACCESS TO CLINICAL TRIALS

7.1. Short-term actions

7.1.1.

Promote Improve patient information and trial visibility: Develop accessible information on nuclear medicine clinical trials and their potential benefits, risks and practical requirements to facilitate informed participation.

Deliverable: European patient-friendly information resource on nuclear medicine clinical trials

7.2. Medium-term actions

7.2.1.

Strengthen patient involvement in trial development: Promote patient involvement in the design, prioritisation and communication of nuclear medicine clinical trials.

Deliverable: European patient advisory mechanism for trial prioritisation, design and communication

7.3. Long-term actions

7.3.1.

Strengthen Promote equitable access to nuclear medicine trials: Develop approaches to reduce geographical and organisational inequalities in patient access to clinical trials across Member States.

Deliverable: framework using the European centre map to identify geographical gaps and facilitate patient referral/network participation

CONCLUSION

Realising the potential of nuclear medicine in precision medicine requires a clinical trial environment that is proportionate, harmonised and enabling. **Regulatory requirements should reflect the actual risks and complexity** of each investigational intervention, without compromising patient safety, scientific quality or radiation protection.

However, **regulatory simplification alone will not be sufficient**: progress also requires stronger infrastructure, access to radiopharmaceuticals, workforce capacity, methodological support, sustainable funding, collaboration and meaningful patient engagement.

Achieving the ambitions set out in this document will require continued cooperation across the community and with our partners and wider stakeholders. The proposed actions and deliverables are a starting point for collective discussion and action, rather than fixed proposals. **We welcome input from all relevant stakeholders and invite organisations and partners to proactively engage with individual deliverables, contribute their expertise and resources, and help shape and take forward their implementation.** The identification of stakeholders and potential leads should therefore remain open and evolve through continued dialogue within and beyond the nuclear medicine community.

Let's continue the conversation: EUaffairs@eanm.org