European Association Nuclear Medicine

EANM Survey on Barriers in Clinical Trials in Nuclear Medicine

June 2026

EANM Introduction

Nuclear Medicine

Nuclear Medicine is a multi-professional, independent, medical discipline based on the application of probes labelled with radionuclides (**radiopharmaceuticals**) to both diagnose and treat various diseases. Its scope encompasses molecular imaging, image-guided procedures, and targeted radionuclide therapy.

Clinical trials involving radiopharmaceuticals are **particularly complex because they combine the requirements of pharmaceutical development, medical imaging, and radiation safety**. Their conduct requires close collaboration between multiple specialists. In addition, the production and use of radioactive compounds are subject to strict manufacturing, logistical, dosimetric, and regulatory requirements, making trial design and implementation more challenging than for conventional medicines.

European Association of Nuclear Medicine

The European Association of Nuclear Medicine (EANM) is a voluntary non-profit association, with an aim to improve public health, as well as to promote science and education in the field of Nuclear Medicine.

- The latest EANM'25 Congress was attended by more than 9,000 participants
- The EANM is registered as a non-profit association in Vienna
- The EANM represents

  -40 member states of the Council of Europe, plus Israel
  -More than 3,000 individual members and 48 corporate members
  (Physicians, Physicists, Chemists, Radiochemists and Technologists)

However, the community outreach goes far beyond these numbers, as well as the boundaries of Europe.

EANM Activities in a nutshell

European Association Nuclear Medicine

1 Advocacy & Workforce Development

Promote recognition of Nuclear Medicine across Europe

- EANM advocacy/policy activities
- INSPIRE recruitment initiative
- Mentorship Programme

2 Education & Professional Training

Expand access to high-quality education and skills development

- ESMIT- European School of Multimodality Imaging and Therapy
- RLT Academy open-access resources

3 Quality & Clinical Excellence

Harmonize and elevate standards of practice

- EARL accreditation programme
- EARL Theranostics Certification

EANM ACT EU Project Group

- Established in June 2025
- Functions under the guidance of EANM Policy and Regulatory Affairs Council
- Consists of EANM Committee Representatives across specialties and countries
- Objectives of the project group:
  - Prepare EANM positioning and priorities on ACT EU
    - What should the EANM prioritise and focus on?
    - What concerns and opportunities should be flagged by the nuclear medicine community?
  - Focus on academic sponsored clinical trials
    - Identify gaps, issues and bottlenecks (regulatory, resourcing, operational) that present challenges for non-commercial sponsors in the conduct of clinical trials.
    - Identify propose pragmatic and harmonised solutions to support non-commercial sponsors.

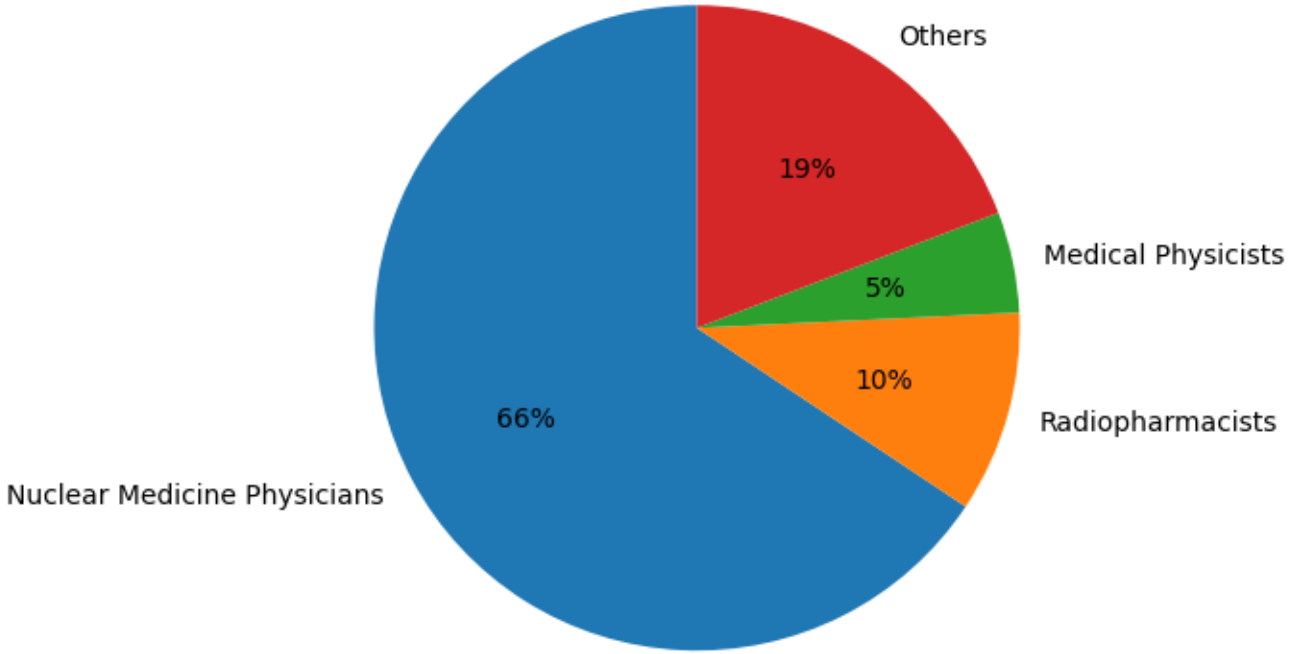
2025 Community Survey

Survey on Barriers in Clinical Trials in Nuclear Medicine

- Aim of the project:
  - Identify key barriers and solutions to run spontaneous/non-profit clinical trials in Nuclear Medicine

- Survey design:
  - 15-question (10 minutes to complete) European survey (Oct-Dec 2025)

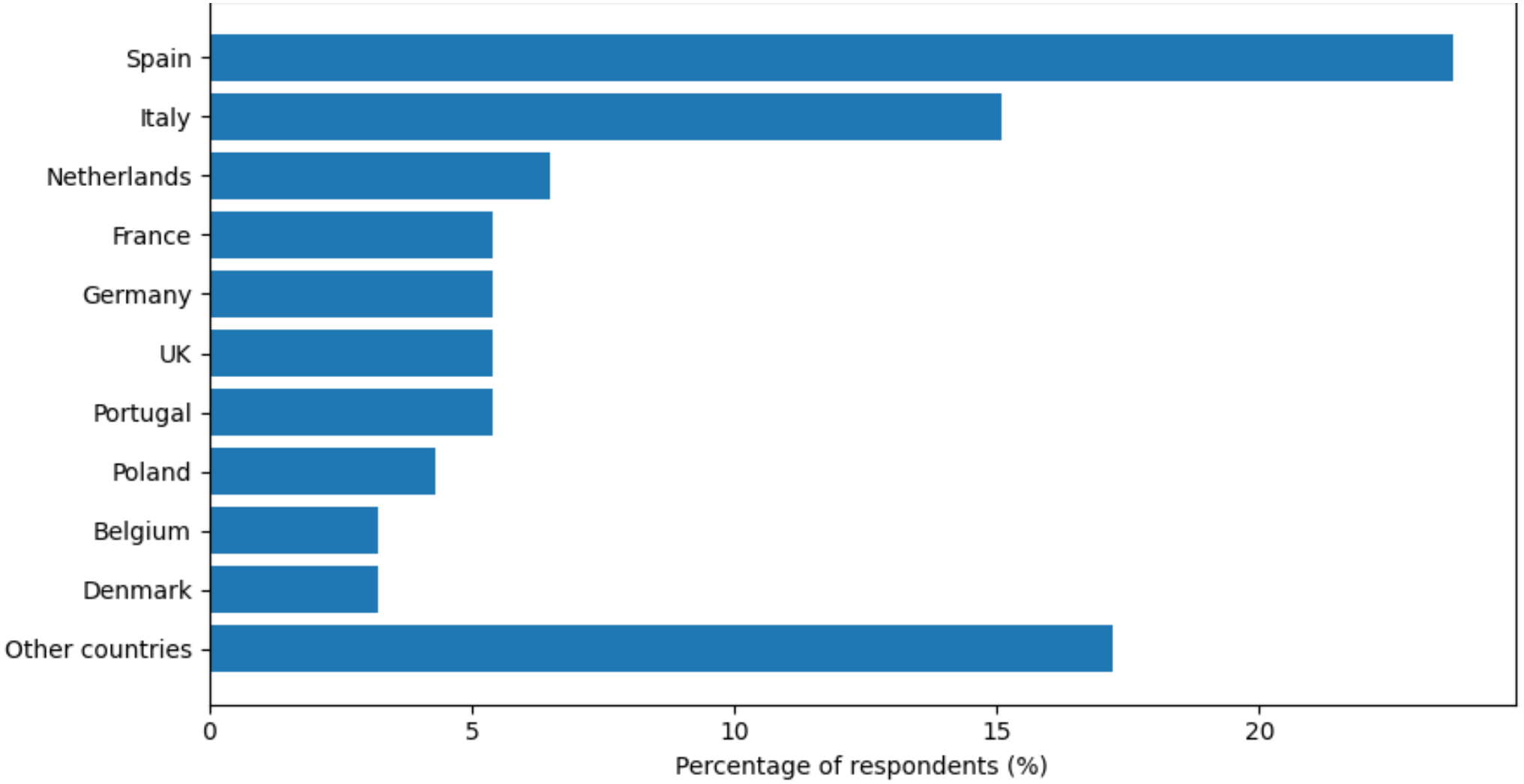
Survey Respondent profile:



68% with >10 years of experience
83% previously directly involved in a non-profit CT
72% with a dedicated CT unit within their Institution

-> experienced, multidisciplinary professionals actively engaged in clinical research

Survey Respondent Geographic Distribution:



Survey Previous experience in non-profit clinical trials in Nuclear Medicine:

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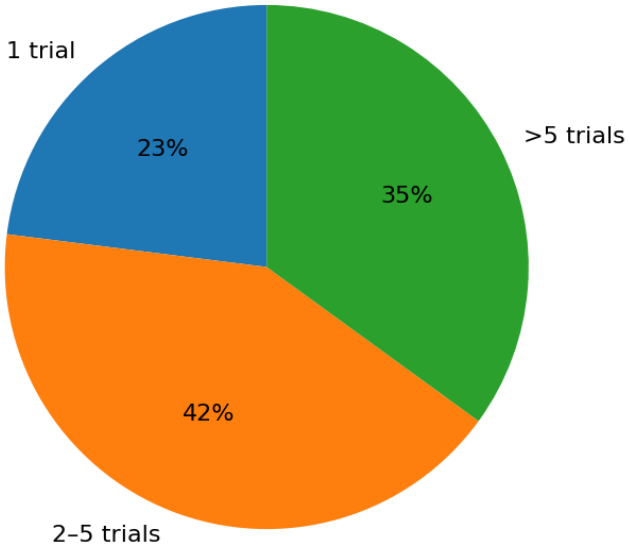
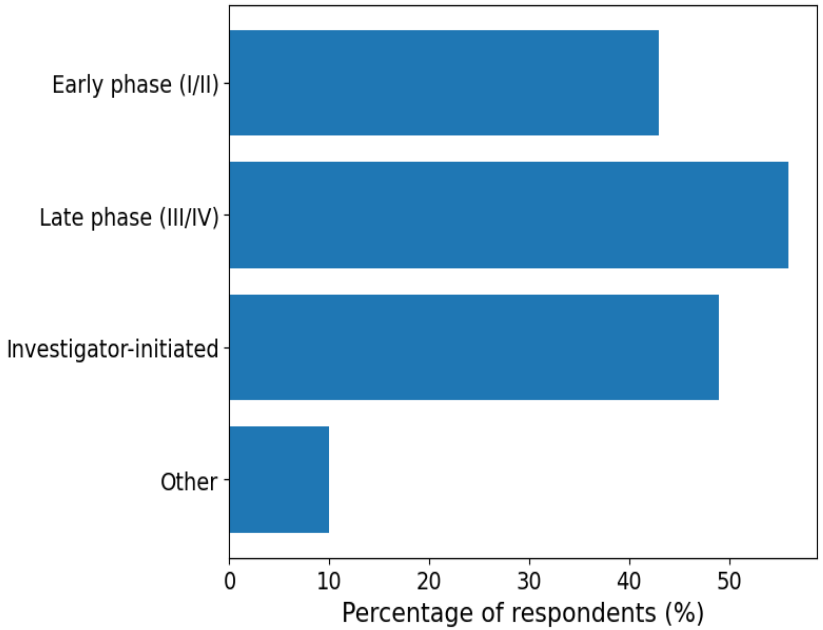
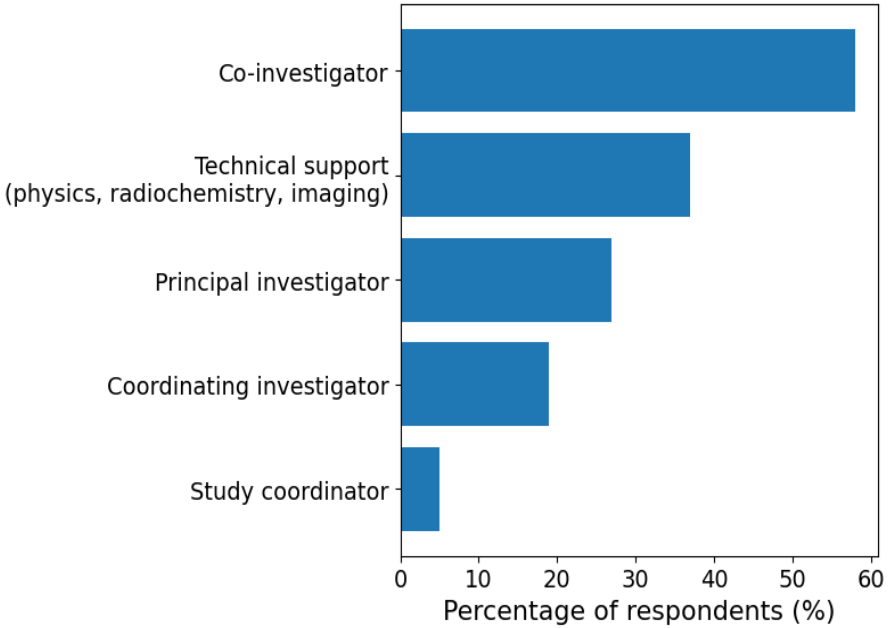
Number of non-profit CT



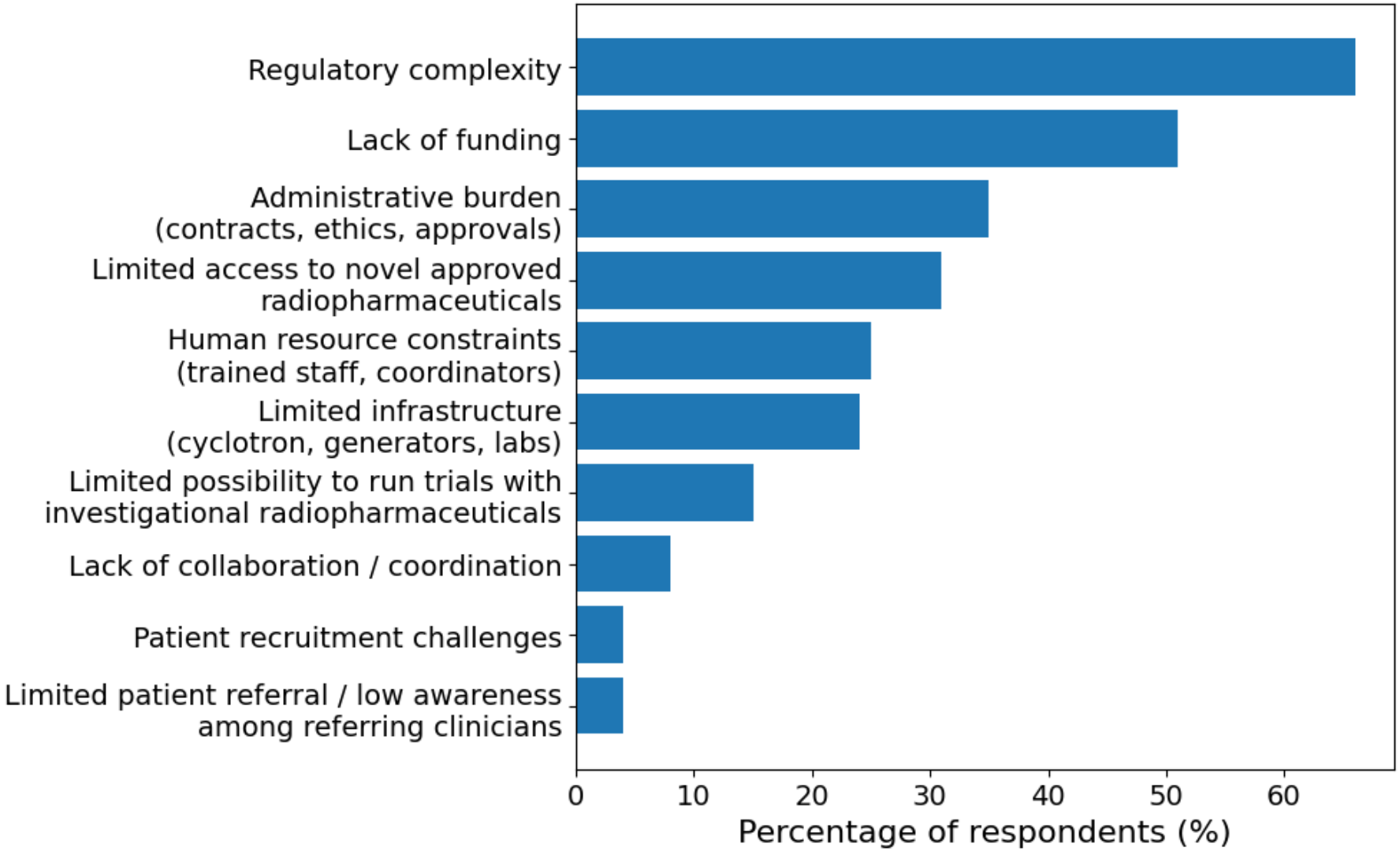
Non-profit CT type



Main roles in previous non-profit CT



Survey Top reported barriers to non-profit clinical trials in Nuclear Medicine:



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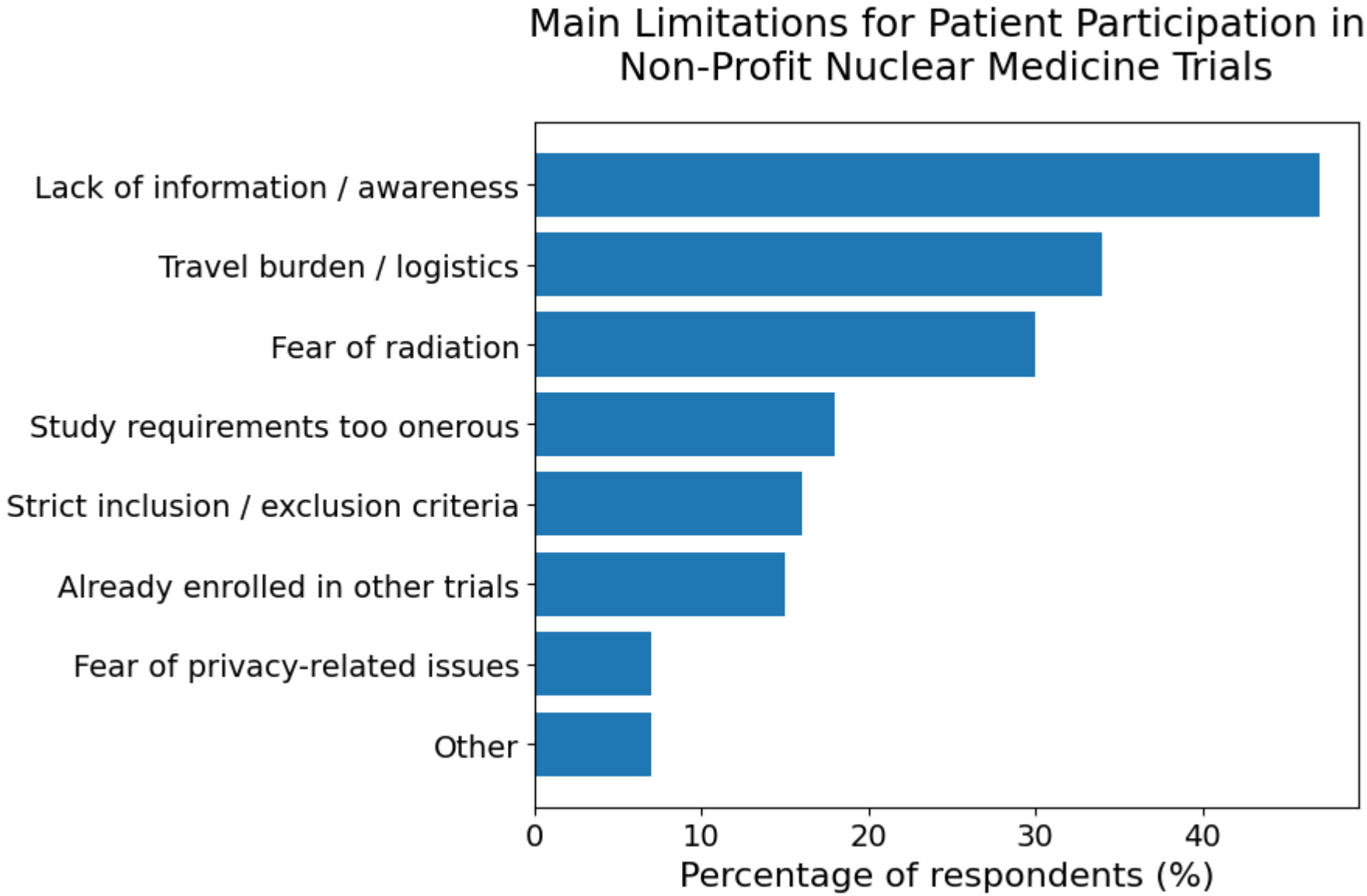
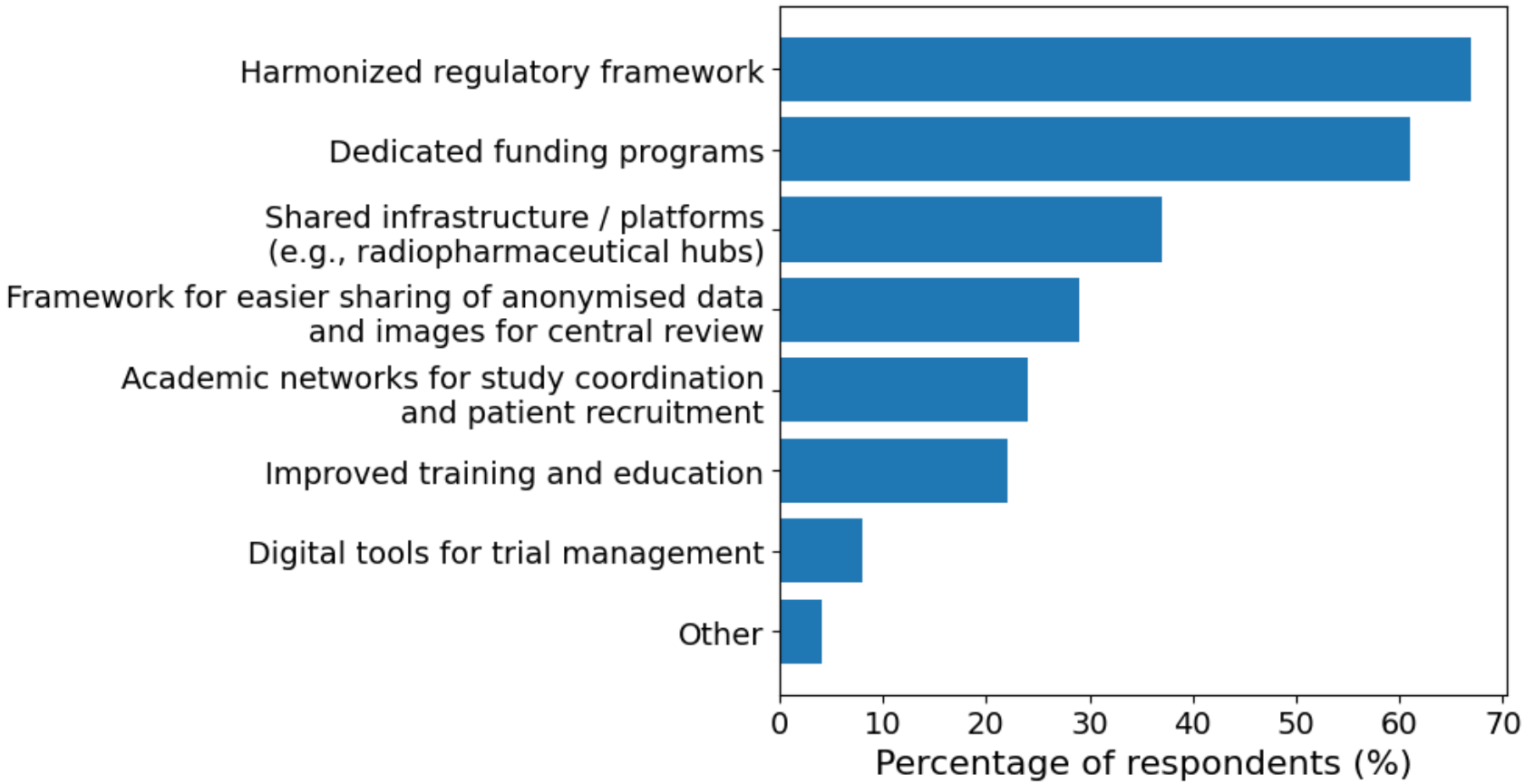
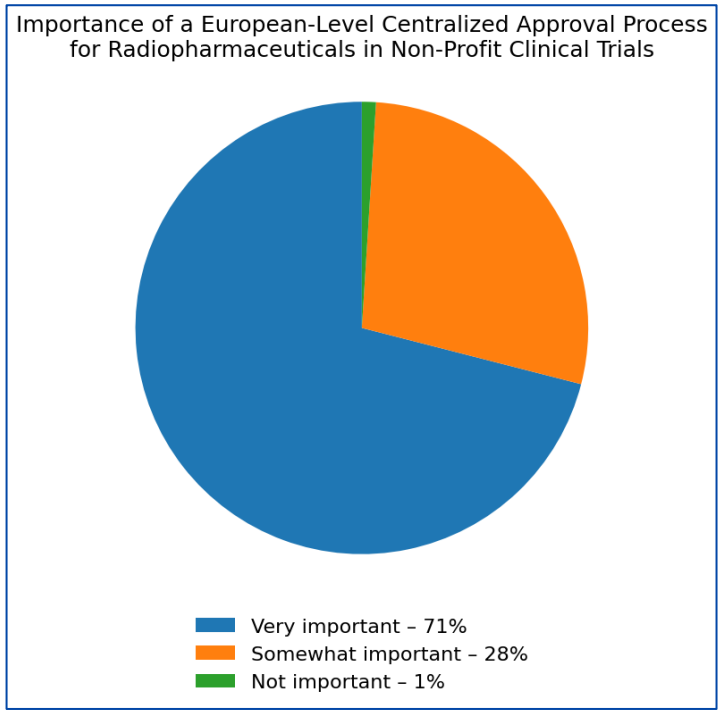


Measures to Improve the Feasibility of Non-Profit Nuclear Medicine Trials in Europe





How to Overcome Barriers
Key Messages from Open-Ended Responses (1)

Regulatory simplification and harmonization

- Regulatory burden is consistently perceived as disproportionate compared with other regions (e.g. EU vs USA)
- Long and fragmented approval processes discourage academic investigators, even when funding is available
- Strong support for EU-level harmonization, streamlined procedures, and fast-track pathways for diagnostic radiopharmaceuticals
- Centralized or coordinated ethical/regulatory approval is seen as beneficial, provided it does not add further bureaucracy

Early and continuous regulatory support

- Investigators highlight the need for regulatory guidance from the earliest phases of trial conception
- Shared protocols, standardized documentation, and harmonized imaging requirements are repeatedly requested
- Clear guidelines for early-phase radiopharmaceutical development (toxicology, GMP/API requirements, first-in-human studies) are considered essential

Infrastructure and access to radiopharmaceuticals

- Limited access to PET/SPECT scanners and novel radiopharmaceuticals restricts participation in multicenter trials
- Dependence on external sites often leads to delays or exclusion from studies
- Respondents support inter-institutional hubs and shared infrastructure models at national or European level

How to Overcome Barriers
Key Messages from Open-Ended Responses (2)

Workforce constraints and role recognition

- Heavy clinical workload and staff shortages limit research engagement
- Nuclear Medicine Technologists are underutilized despite representing the largest workforce
- Strong call to formally involve and empower technologists, including opportunities to act as investigators or trial leads
- Dedicated funding for research-protected time and trial-specific staff is considered crucial

Coordination, equity, and collaboration

- Insufficient dissemination of calls for participation limits involvement, particularly in trial design phases
- Respondents report unequal participation and centralization of studies in a small number of countries
- Strong support for European academic networks, improved coordination, and collaboration with established research organizations (e.g. EORTC)
- Collaboration with industry is encouraged, particularly for precursor supply and early radiopharmaceutical development

-> Overall, respondents describe a complex, cumulative pathway in which regulatory, organisational, and workforce barriers interact, often discouraging academic investigators from initiating non-profit CT

Survey Bullet points take-home Messages

Non-profit clinical trials in Nuclear Medicine are limited predominantly by regulatory and organisational constraints, rather than scientific feasibility.

Regulatory fragmentation across Europe represents the main obstacle to multicenter academic studies.

Ethical and regulatory approval is consistently identified as the most critical step in the trial pathway.

Limited access to radiopharmaceuticals, infrastructure, and protected research time (i.e. formally allocated time away from routine clinical duties) further restricts participation.

There is a broad consensus among professionals on the need for:

- European regulatory harmonisation
- Dedicated funding
- Shared infrastructures and networks

Publication based on the survey results expected in autumn 2026

Thank you!

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