EU Policy Symposium 2

Policy & Regulatory Affairs Council
Tuesday, October 20, 15:00–16:30

Session Title

Accelerating Clinical Trials in Nuclear Medicine: From Regulation to Implementation

Co-Chairs

Wim Oyen (Nijmegen, Netherlands)
Karolien Goffin (Leuven, Belgium)

Programme

15:00-15:05	Introduction by the Co-Chairs
15:05-15:25	**Marianne Lunzer (Vienna, Austria):** ACT EU: Building a More Efficient and Harmonised Environment for Clinical Trials in Europe
15:25-15:45	**Laura Evangelista** (Milan, Italy): Breaking Down Barriers: Advancing Non-Commercial Clinical Trials in Nuclear Medicine Across Europe
15:45-16:05	**Winette Van der Graaf** (Amsterdam, Netherlands): From Protocol to Patient: Practical Lessons from Multinational Academic Trials in Europe
16:05-16:30	Moderated Multi-Stakeholder Panel Discussion - Turning Ambition Into Action: What Will it Take to Accelerate Nuclear Medicine Trials in Europe? (All speakers and invited speakers): **Nathalie Albert** (Munich, Germany)

Summary

Clinical trials are essential to bringing innovative radiopharmaceuticals to patients, yet significant regulatory, operational and resource-related barriers continue to hinder the conduct of academic and multinational studies across Europe. This session will explore how recent European initiatives, including the Clinical Trials Regulation and ACT EU, are shaping the clinical research landscape and what further actions are needed to accelerate innovation in nuclear medicine. Bringing together regulators, academic researchers and clinical experts, the discussion will examine both policy developments and practical implementation challenges, with a particular focus on strengthening Europe's capacity to deliver high-quality multinational clinical trials and improve patient access to novel diagnostics and therapies.

Educational objectives

- Describe recent European regulatory initiatives, including ACT EU, aimed at improving the conduct of clinical trials across Europe.
- Identify the key barriers affecting academic and non-commercial clinical trials in nuclear medicine and radiopharmaceutical research.
- Discuss opportunities for collaboration between regulators, scientific societies, trial networks and researchers to accelerate clinical research and patient access to innovation in nuclear medicine.

Key Words

Clinical Trials; Radiopharmaceuticals; ACT EU; Academic Research.