



Workshop agenda

Research and Innovation for Sustainable Medical Radionuclide Supply in the EU

JRC Karlsruhe

22 November 2023

08:00-09:30 Arrival at the Joint Research Centre & coffee

09:30-10:00 Welcome remarks

Chair: Ulla Engelmann (Dir JRC.G)

Commissioner-designate (t.b.c.)

Bernard Magenhann (DDG JRC)

Jose Manuel Perez (Spanish Presidency, CIEMAT)

10:00-11:15 Topical session 1 – Landscape and challenges for medical radionuclide supply and research in the EU

Chair: Remigiusz Baranczyk (ESA)

- 10:00–10:15 Racing against time: the radiopharmaceutical supply chain
(Paola Erba, EANM)
- 10:15–10:30 Commission action on medical isotopes – the SAMIRA Action Plan
(Jan Panek, DG ENER)
- 10:30–10:45 Monitoring of irradiation capacities and supply of medical radionuclides
(Bernard Ponsard, NMEU)
- 10:45–11:00 Ongoing initiatives to secure supply of medicines in the EU and to prevent shortages of medicinal products
(Maria Alcaraz, EMA)
- 11:00–11:15 Q&A with all speakers

11:15-11:45 Coffee break

11:45-13:00 Topical session 2 – The industrial and innovative nuclear infrastructure landscape for medical radionuclide research and production

Chair: Alfred Morgenstern (JRC.G.II.6)

- 11:45–12:00 The present and future reactor landscape in the Netherlands for the production of medical radionuclides
(Ronald Schram, NRG)
- 12:00–12:15 The BR2 reactor and the future MYRRHA facility – The role of Belgium for medical radionuclide production
(Hamid Abderrahim, SCK-CEN)
- 12:15–12:30 The Jules Horowitz Reactor in the French landscape of medical radionuclides
(Marion Libessart, JHR)
- 12:30-12:45 Industrial infrastructure for the production of medical radionuclides
(Harrie Buurlage, SHINE Medical)
- 12:45-13:00 Q&A with all speakers

13:00-14:00 Lunch break

14:00-15:30 **Topical session 3 – Research and development in Europe on medical radionuclides**

Chair: Domenico Rossetti di Valdalbero (DG RTD)

- 14:00-14:15 PRISMAP, towards a sustainable European medical radionuclides programme (Thierry Stora, CERN)
- 14:15-14:30 Strengthening the European chain of supply for next-generation medical radionuclides (Renata Mikołajczak, Polatom)
- 14:30-14:45 Highlights from JRC research on medical radionuclides (Alban Kellerbauer, JRC.G.II.6)
- 14:45-15:00 R&D on Radium-226 for Actinium-225 production (Sven van den Berghe, Pantera)
- 15:00-15:15 Novel alpha- and Auger-emitting radionuclides for medical applications (Bertrand Morel, Orano)
- 15:15-15:30 Q&A with all speakers

15:30-16:00 Coffee break

16:00-17:30 **Break-out rooms / Survey on line / Discussion – Synergies to keep the EU at the forefront of R&I to secure radionuclide supply**

Chairs: Margarida Goulart (HoU JRC.02) and Rachel Eloirdi (HoU JRC.G.II.6)

- Breakout room 1 (chaired by JRC)
- Breakout room 2 (chaired by OECD/NEA)
- Breakout room 3 (Chaired by DG ENER)

17:30-17:45 **Wrap-up and closing remarks**

Outlook: Alberto Fernandez Fernandez (Belgian Presidency 1st sem. 2024)

Closing remarks: Bernard Magenhann (DDG JRC)

Background

Medical applications of nuclear science: Developments and challenges

The medical applications of ionizing radiations have developed considerably over the past few decades and offer promising opportunities for European patients, achieving significant advances for the diagnosis and treatment of several important and recurring diseases like cancer, cardio-vascular and brain diseases.

Extensive research in therapeutic nuclear medicine, along with accelerated clinical trials and product development, has focused on various cancer types such as neuroendocrine and prostate cancer. These advancements have led to the emergence of targeted radioligand therapy (TRT), offering innovative approaches to combat tumours. In addition, theranostics (using the same drug for both diagnosis and therapy) is expected to become an essential tool, offering immense potential in the battle against cancer.

The EU is a significant global supplier of medical radionuclides, producing 60% of the world's imaging radionuclides. However, more **research and development (R&D)** is needed to explore new radionuclides and production methods for therapeutic radionuclides that are in strong demand.

European Commission initiative in the field of research

On 13 February 2023, former Commissioner Mariya Gabriel chaired the Third High-Level Nuclear Roundtable on Medical Applications and Research Infrastructures to strengthen the support of nuclear research and innovation to life-saving health technologies. In this endeavour, the Euratom programme is aligning some of its objectives with other initiatives of the EU such as the **EU's Beating Cancer Plan, the SAMIRA Action Plan** and, in general, **health innovation**.

A first stakeholder consultation workshop on "Translating radiotheranostics cancer research into clinical practice in Europe" took place on 27 April 2023 at JRC Ispra, to reflect on an innovative combination of diagnosis and therapy based on radiopharmaceuticals. As nuclear medicine is also dependent on an upskilled and dedicated workforce, the second workshop, organized with the European Nuclear Education Network (ENEN) on 24 October 2023 at JRC Petten, will focus on nuclear competences and skills, aiming at attracting young talents to the nuclear sector for health applications.

The third workshop, taking place on 22 November 2023 at JRC Karlsruhe, will focus on research and innovation and their importance in medical radionuclide applications, in particular to ensure the sustainability of supply, equal access and quality/safety in the use of radiopharmaceuticals in the EU. A key aspect will be fostering research collaboration among relevant nuclear infrastructures and partnerships involved in bringing these technologies to patients.

Scope and objectives

This workshop will highlight the role of infrastructures and innovation in enabling breakthroughs in nuclear science for health applications. It will explore challenges in R&D for nuclear medicine and its translation into the market. Novel production routes will be presented along with an overview of existing and new nuclear infrastructures. The sustainable development and supply of radiopharmaceuticals will be a key focus to maintain the EU's long-term leadership in medical radionuclide supply.

Key stakeholders from academia, industry, research, and health policy makers will be in attendance to discuss optimal synergies that can keep the EU at the forefront of research and innovation, ensuring secure radionuclide supply and expediting the process from R&D of radiopharmaceuticals to clinical trials. The event will thrive to identify challenges hindering the efficiency of current production methods or hampering the unfolding of alternative and innovative pathways for medical radionuclides. It will also aim to foster research collaboration among relevant facilities and partnerships involved in the topic.

Science for policy

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