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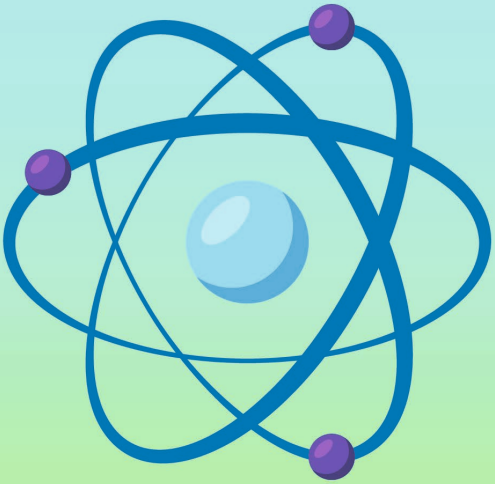
Small Modular Reactors and Medical Applications of Nuclear Technologies



European Nuclear Roundtable

Research and Innovation

Small Modular Reactors and Medical Applications of Nuclear Technologies –
A focus on Research and Artificial Intelligence

European Commission
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EUROPEAN COMMISSION

Small Modular Reactors and Medical Applications of Nuclear Technologies

A focus on Research and Artificial Intelligence

High-level European Nuclear Roundtable

edited by Domenico Rossetti di Valdalbero and Maria Papadopoulou

2022

Directorate-General for Research and Innovation
Euratom Research and Training Programme

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INTRODUCTION AND ACKNOWLEDGMENTS

This publication is the proceedings of the second High-Level Nuclear Roundtable convened on 15 March 2022 by European Commissioner Mariya Gabriel in charge of Research and Innovation. The Roundtable was organised by the Euratom Research Unit of DG RTD and Health colleagues in co-creation with DG ENER and JRC together with European stakeholders (Foratom, SNETP, EANM and MEENAS).

The objective of the Roundtable was to discuss two key areas that require Research and Innovation actions: Small Modular Reactors and Medical applications using nuclear technologies. For both areas, Artificial Intelligence is identified as a common denominator that could drive innovation and cross-fertilisation between fields.

This Roundtable was made possible thanks to the initiative of Commissioner Mariya Gabriel and her Cabinet, especially Carlos Morais, to Rosalinde van der Vlies, Director of the Clean Planet Directorate that moderated the discussion with the stakeholders and Elena Righi-Steele, Head of Unit of Euratom Research in DG RTD that supported the Roundtable process since the early phase.

The main speakers have to be thanked for their interventions in the Roundtable: Yves Desbazeille, Director-General of FORATOM, Bernard Salha, President of SNETP and CTO of EDF, and Eero Vesaoja, Director of Nuclear R&D of Fortum that have given their insights on SMRs. Thank you to Jolanta Kunikowska, Professor at the Warsaw Medical University and President of EANM, Hildegarde Vandenhove, Director at SCK-CEN and President of MEENAS, and Margarita Kirienko, Research Physician at the National Cancer Institute in Milan for their insights on medical applications.

Particular thanks also to the two Rapporteurs of the sessions: Zsolt Fülöp from the Hungarian National Research Infrastructure Committee that has been the rapporteur of the first session and Sonya Sergieva from Sofia Cancer Centre that has drawn the conclusions of the second session.

A special thank you to all 40 participants of the Roundtable and in particular to the stakeholders below for their valuable contributions during the preparation of the Roundtable: Berta Picamal and Andrei Goicea from FORATOM, Abderrahim Al Mazouzi from SNETP, Michael Lassmann, Amélie de Martini, Sonja Niederkofler, Andrzej Wojcik, Christoph Hoeschen and Daniel Borek from EANM and MEENAS.

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Rachel Eloirdi from JRC; Michael Huebel, Gianfranco Brunetti, Ghislain Pascal, Kolos Molnar, Georgi Simeonov and Sophie Paultre from DG ENER.

RESEARCH, INNOVATION AND SKILLS FOR ENERGY TRANSITION AND MODERN HEALTHCARE IN THE EU

Mariya Gabriel, European Commissioner for Innovation, Research, Culture, Education and Youth

A High-Level Nuclear Roundtable was convened on 15 March 2022 with stakeholders from the nuclear and medical sectors to explore potential synergies across fields from which European citizens can benefit, starting with energy and health. Today's challenging times require unity and urgent, strong and solidary action.

Energy Transition

Regarding the energy transition, Research and Innovation (R&I) has growing relevance to the required acceleration to diversify EU sources and reduce dependency, in particular from unreliable partners. This is not only valid from a medium-term perspective but it is very much valid from an emergency perspective as well. The EU should accelerate its path in view of reducing by 55% its greenhouse gas emissions while ensuring independence in terms of energy sources and technologies. For this purpose, all carbon-neutral technologies are needed. It is up to the Member States to choose their energy mix. The Commission approved in February 2022 the complementary Delegated Act on the Taxonomy Regulation[1], which aims to guide private investments to achieve climate neutrality. Nuclear technologies are included in this Delegated Act as a transition source.

Small Modular Reactors

Today, half of the Member States[2] have opted either for large-scale nuclear facilities, or future Small Modular Reactors (SMRs). Because they are smaller in size and modular, SMRs promise to be safer, cheaper and easier to build and operate[3]. As a result, they could bring electricity and heat to regions where economic, geographical or grid-related constraints impede the economic viability of large conventional power plants. In several EU Member

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[1] The EU taxonomy – Complementary Climate Delegated Act to accelerate decarbonisation: https://ec.europa.eu/info/publications/220202-sustainable-finance-taxonomy-complementary-climate-delegated-act_en.

[2] In total, large reactors or SMR designs are planned by private enterprises in 14 Member States. Currently, 13 Member States have operational nuclear power plants (Belgium, Bulgaria, Czech Republic, Finland, France, Germany, Hungary, the Netherlands, Romania, Slovakia, Slovenia, Spain and Sweden) of which 3 plan nuclear phase-outs by 2030 (Belgium, Germany, Spain) and 8 are building or planning new reactors (Bulgaria, Czechia, Finland, France, Hungary, Poland, Romania and Slovakia). In addition, companies from several Member States are developing SMR designs (Czech Republic, Denmark, France, Italy, Luxembourg, Poland and Sweden).

[3] Larger-scale nuclear facilities are conventional facilities typically of 1000 MWe. Future Small Modular Reactors (SMRs) will be between 10 to 300 MWe. Because of their smaller size, SMRs can rely on natural circulation allowing simplified design, and foresee modularity and series production. The current Technology Readiness Level (TRL) of SMRs divides them in two groups: 1) the Light Water (LW) SMRs, which are based largely on existing proven technology but rely on natural circulation allowing simplified design and could be deployed in the next decade; 2) the Advanced Modular Reactors, which are based on innovative concepts that have still to be investigated and could therefore be deployed only beyond 2040.

States, SMRs may be an option to switch from coal power plants to decarbonized electricity. Innovative SMR designs are expected to display enhanced safety performance through passive and inherent safety features.

The Euratom Programme has been funding several research actions on nuclear safety, advanced materials and licensing for new types of reactors, including SMRs[4]. The Commission services (DG ENER, DG R&I and JRC) are exploring how to deploy SMRs in Europe, focusing on R&D issues that will promote industrial cooperation and build a stronger EU industry[5]. The Euratom Work Programme 2021-2022 is funding several innovative cross-sectoral projects to promote synergies and new applications between nuclear and other sectors for EUR 10 M. These low-carbon nuclear technologies could benefit from R&I developments in Artificial Intelligence (AI) combined with high-performance computing. AI in the nuclear sector has been expanding considerably in the last few years. The know-how and expertise that is gained from applying AI-enabled digital tools to the nuclear industry have the potential to be transferred to other sectors.

Nuclear and Health

The area of health best exemplifies how important it is to build bridges between the nuclear sector and other sectors. Radiological and nuclear technologies play a crucial role in modern healthcare. They are widely used for diagnosing and treating diseases, such as cancer, cardiovascular and neurological diseases; and more recently, to complement the diagnosis of COVID-19 pneumonia[6]. In the EU, each year around 500 million medical procedures use ionising radiation. And around 50% of cancer patients benefit from radiotherapy.

At the same time, the therapeutic uses of nuclear medicine are constantly expanding and the volume of healthcare data is expected to continue growing in the years ahead, which unlocks the potential for better and personalised patient care. The EU is the world's leading supplier of medical radio-nuclides with a 60% market share of the global demand for some of the most widely used radioisotopes in diagnostics, therapeutics or the combined approaches of theranostics (therapeutics and diagnostics). The safety and security of the supply of radioisotopes to patients should continue to be ensured. Furthermore, isotope production, equal access to medical procedures for patients and supporting the development of new treatments, are vital for the EU. Likewise, the highest-quality radiation technologies are needed to ensure the safety of new screening, treatment and care options. These are key elements in providing care and protection for all – citizens, including patients, medical staff and the public.

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[4] Examples of current Euratom-funded projects focusing on SMRs nuclear safety are ELSMOR, McSAFER, CC-SMART, GEMINI+ with a total Euratom contribution of EUR 15 M. DG ENER established in December 2021 the Inter-Service Working Group (ISWG) to prepare and coordinate EC representation in view of launching a "European Small Modular Reactors (SMRs) Partnership" with EU stakeholders (industry, research organisation, European Regulators).

[5] DG ENER established in December 2021 the Inter-Service Working Group (ISWG) to prepare and coordinate EC representation in view of launching a "European Small Modular Reactors (SMRs) Partnership" with EU stakeholders (industry, research organisation, European Regulators) with a severe form of COVID-19 or pre-existing chronic lung disease.

[6] Chest imaging, including chest radiography and computed tomography (CT), has been also considered to complement the clinical evaluation of patients diagnosed with COVID-19, in particular for patients.

The current Euratom Research and Training Programme for 2021-2025 puts a stronger emphasis on supporting research for the protection of patients benefiting from medical diagnoses and treatments using radiation sources. The Euratom Programme of 2021-2022 contributes to Europe's Beating Cancer Plan and directly supports the Commission initiative SAMIRA[7] and the EU Mission on Cancer. The programme covers research on the safe use and reliable supply of medical radioisotopes[8]. In addition, it is reinforcing the synergies between Euratom Research and the Health cluster of Horizon Europe, with a co-funded European Partnership on Radiation Protection to be launched by mid-2022[9].

Artificial Intelligence, Education and Training

In this context, using new digital technologies, such as AI to improve the quality and analysis of medical images, could bring tangible benefits to patients by improving the quality and safety of their care, speeding up dose optimisation and supporting more efficient healthcare systems. Combined with High-Performance Computing, AI-based tools can help rapidly process large amounts of health data and increase the quality of for example risk-based cancer screening, diagnosis, and patient care. These could in turn enable a more targeted screening and a more personalised and precise treatment.

A decisive aspect of the future is the development of advanced skills as a key condition for European autonomy. Both the energy transition and modern healthcare will be more effective in socio-economic terms by leveraging the great potential of research, innovation and the creation of highly skilled people through education. The EU needs to master the technologies with world-leading infrastructures to be built in the coming decades, but also technologies that will improve security and safety, which are already subject to the highest requirements. A constant and long-term effort is needed to retain, maintain and develop the best knowledge base in the EU. These needs will grow as nuclear technologies expand into medicine, for instance with advanced imaging systems and cancer treatment infrastructures.

All Member States will benefit from strategic investments in competencies and knowledge of nuclear technologies that offer possibilities for climate change mitigation and increased security. There is also the broader international context in the nuclear supply chain that is quickly changing. Any obstacle to investments in know-how is risky and best practice is avoiding dependencies on technologies that are not domestically produced and know-how is low. The EU should be well represented in international regulations and standards, to define the rigorous plans to handle emergencies in the EU or third countries.

Roundtable Outcomes

This publication summarises the outcomes of the Roundtable discussion with nuclear stakeholders in the areas of energy and health, targeting the two key questions below on

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[7] Strategic Agenda for Medical Ionising Radiation Applications: https://ec.europa.eu/commission/presscorner/detail/en/IP_21_265.
[8] Safe use and reliable supply of medical radionuclides (cf. Topic Horizon-Euratom-2021-NRT-01-10) with EUR 4 M.
[9] European Partnership for research in radiation protection and detection of ionising radiation (Topic Horizon-Euratom-2021-NRT-01-09) with EUR 30 M.

small modular reactors and medical applications using nuclear technologies. For both areas, Artificial Intelligence (AI) is identified as a common denominator that could drive innovation and cross-fertilisation between fields:

- How can AI and advanced robotics support developing novel manufacturing techniques, reducing human interventions in nuclear operation, and enhancing safety, waste management and decommissioning?
- How can AI and digital tools help us improve medical diagnosis and radiation protection and make more informed decisions about medical procedures and a more precise health treatment planning?

SMALL MODULAR REACTORS AND ARTIFICIAL INTELLIGENCE

PREPARING FOR A EUROPEAN SMR

Yves Desbazeille, Director General of FORATOM

The 2050 European Roadmap considered nuclear, together with the undenied role of renewable energy sources (RES), as the backbone of a low-carbon energy mix necessary to achieve carbon neutrality. Nuclear will continue to be part of the landscape by at least 15% of the total energy production. For this to be a reality, there are several factors to take into consideration. On the one hand, the existing fleet needs to continue operating. Long-term operation (LTO) programs, such as the one in France with the so-called 'Grand Carénage', need to be supported. On the other hand, we have to accelerate the development of newer technologies that can respond to very specific needs. Therefore, timely development of SMRs is key. In the light of the unfortunate events that take place today, reconsidering the security of supply and keeping energy prices under control, are crucial for the EU economy.

Towards a European SMR Partnership

Regarding SMRs, during the first event organised in late October 2019 with the high-level Roundtable between the European Commission and the US, it became obvious that Europe needed to step in and up. That first event was followed by an EU initiative with the "First EU Workshop on SMRs" end of June 2021, where it was recognised that SMRs have a strong potential to be one of the elements that can contribute to the EU's 2050 climate targets, decarbonised energy sector under the Green Deal, and the European economic recovery and industrial resilience [10]. For SMRs to become an actual contributor to those aims, their use in Europe should start in the next decade, i.e. early 2030s. Current prospects in several EU Member States show that SMRs could contribute to the replacement of retired electricity generation capacity or be used for other applications such as industrial co-generation (industrial heat), district heating, and hydrogen production. And more recently, announcements from different Member States show that SMRs will become a reality.

The 2021 workshop paved the way for launching the preparations for a European SMR Partnership where FORATOM[11] and its industry stakeholders, SNETP and its research and technological organisations as well as all interested parties, from potential customers including utilities and Member States, together with EU policy-makers and regulators start collaborating with the aim to create enabling conditions and identifying potential constraints for the first European SMRs starting operation in the initial years of the next decade. The Partnership has started the preparatory work in a step-wise approach with a first stage that

[10] Speech by Commissioner Simson at the World Nuclear Exhibition: https://ec.europa.eu/commission/commissioners/2019-2024/simson/announcements/speech-commissioner-simson-world-nuclear-exhibition_en.
[11] FORATOM is the trade association for the nuclear energy industry in Europe: https://www.foratom.org/.

should give general direction in drafting and rolling out of a roadmap. To do so, different work-streams have been established.

Market integration and deployment

The main objectives of this work-stream would be to characterize the European markets and the export markets in a quantitative way, that is to say, to examine future market needs for SMRs (flexibility and system services, in a context of high RES deployment), competitiveness, SMRs as technology replacing coal plants, SMRs potential co-generation (non-power) applications for hydrogen production, desalination, district and process heating, etc. The deliverable will be quantitative market studies. It is also crucial that public perception is addressed, and this work-stream will also look into public opinion of SMRs and how their deployment is perceived.

Licensing

The regulatory aspect is of crucial importance and needs to be addressed with no further delay to see SMRs in Europe in the next decade. ENSREG and its members have positively responded to the call by the stakeholders in the Partnership and have had their first meeting in late February 2022. The aim is to focus on streamlining nuclear safety licensing processes in interested EU countries in a way that the same SMR design could comply without significant modifications with the regulations set by these different European nuclear regulatory authorities, without hampering their prerogatives. This work-stream would identify the elements for establishing a licensing process based on commonly accepted safety assessments from different ENSREG members interested in the licensing of the same SMR design.

Financing and partnership

Financing is key and the tasks entrusted to this work-stream would be to explore and identify all possible options for financing European SMRs, from support to R&D developments, to demonstrators up to industrial deployment, including EU and national instruments, (e.g. conditions for a Private Public Partnership at EU level) and will define the needs for a conducive investment environment and framework for SMRs in Europe.

Supply Chain adaptation

The main objectives of this work-stream are to identify specific needs for SMR manufacturing and designs, analyse the standardisation potential of SMRs, analyse the potential use of non-nuclear standard components, identify ways to maximise new tools and methods in SMRs manufacture and through-life operation, instrumentation and maintenance, including digitalisation, novel techniques, etc. The work shall focus on the European supply chain.

Innovation, Research and Development

Innovation, research and development are at the heart of all successful initiatives in the industry. This work-stream will seek to define a comprehensive R&D&I strategic agenda and roadmap coherent with market needs, licensing requirements, supply chain readiness and sustainability for SMRs development and their use for various applications (heat, hydrogen, etc.). It should also identify the needed facilities to perform this programme, and set up a coherent and consistent training and education programme.

RESEARCH AND INNOVATION IN ACTION FOR SMRS

Bernard Salha, President of Sustainable Nuclear Energy Technology Platform (SNETP) and CTO of Electricité de France (EDF)

The recent development of the SMR ambition sets a new challenge for the nuclear industry in Europe. For SMRs to become actual contributors, their deployment in Europe should start in the next decade. Europe has unique experience and expertise in nuclear technology, including significant research and development capabilities, therefore Europe can play a key role in developing safe and competitive SMRs. The European SMR Partnership will allow the establishment of a strong collaboration scheme involving industry stakeholders, research and technological organisations, interested customers i.e. utilities and Member States, as well as European policymakers and regulators. Support from the Commission Services is vital to deliver on this important technology and to promote a European SMR 'domestic' programme.

There is a critical need to ensure a high continuity in policy from (1) long-term operation of existing nuclear power plant (now), to (2) new commercial light water reactors (2030 and beyond) followed by (3) commercial advanced modular reactors (beyond 2050). These milestones have two main objectives: first to reach net-zero by 2050 and then to ensure the overall sustainability of the nuclear industry, optimizing fresh uranium supply and waste disposal.

R&I opportunities and challenges for SMRs

SNETP[12] has been active in the R&D&I related to SMRs for more than a decade thanks to the support of the Euratom programs, from FP7 to H2020. Recently, more than five projects related to SMR technologies have been evaluated positively for Euratom Research and Training funding and will be launched by mid-2022. However, as the allocated budget of the Euratom Research and Training Program is limited, many projects evaluated as excellent will not be funded. Therefore, resources should be focused mainly on the most mature SMR designs to be deployed in the next decade to get real leverage to tackle climate change.

Beyond their technical merit, SMRs are a new business model which may represent a key enabler towards an efficient energy transition, provided they are supported by a strong effort of R&D&I and training of young staff. SMRs are well adapted to replace small size coal power plants which are quite numerous worldwide. They may be better suited for the generation of industrial and residential heat, desalination, waste recycling, or hydrogen and synthetic fuel production. Additionally, SMRs are well-suited for remote or small grids where the deployment of their larger counterparts would not be practical.

Conditions of success for SMRs in a Digital and AI Era

SMRs are the first nuclear products to be developed in a new digital and artificial intelligence era. The use of artificial intelligence can be instrumental in guiding innovation for nuclear energy either in its independent operation or in cogeneration with renewables:

[12] Sustainable Nuclear Energy Technology Platform: https://snetp.eu/.

Digital tools provide higher collaboration, reactivity, agility, and innovative thinking that would decrease the time-to-market of innovative processes.

Digitalisation helps increase productivity, optimize the inspection and maintenance, plan for radioprotection of workers and last but not least allows a continuous environmental assessment.

However, the adaptation and deployment of these new tools require a set of conditions to be fulfilled:

- Skills and competencies: SMRs as innovative products can be highly attractive for the involvement of the young generation from the design to the realisation.
- Up to date research infrastructures: allow the experimental verification and validation of these tools as the nuclear sector is highly regulated and safety the first priority.
- Long term visibility of a consistent R&D&I program: to define clear objectives and adequate milestones and KPIs to allow focused coordination between all interested stakeholders being R&D centres, industries, regulators and SMEs.
- Promotion of ‘European models of SMR’: models designed, built and operated with EU companies and staff to a very large extent
- Reaching a strategic EU autonomy on European SMR models: to have a free autonomy of decision within EU member states about access to critical data, design, licensing or equipment of these «European SMR models», including for export outside EU.

More collaboration between the nuclear sector and other industrial sectors in R&D&I is needed regarding enabling technologies such as digital, materials, environment, censoring, cybersecurity and others. The aim is to ensure that nuclear power, a carbon-neutral energy source, continues to fulfil its pivotal role in the fight against climate change together with renewable power through implementing cross-cutting and cross-sectorial technologies.

SMRS IN A NEW DIGITAL AND AI ERA

Eero Vesaoja, Director of Nuclear R&D of Fortum

Given the recent turns of events in sustainable finance and security of supply questions, various countries, utilities and industrial companies look towards small modular reactors playing an important role in their plans. For the companies ordering and operating such facilities, some of the main concerns are the project risks and competitiveness.

Innovation to reduce project risks

- Management of complex safety-critical projects: Delays and cost-overruns have been typical for safety-critical and mega-scale projects. Here, SMRs can offer part of the solution with a particular focus on how to organize and manage the projects and their supply chains cost-effectively. Similar innovations are relevant to the aerospace industry.
- The construction of high-quality civil structures: High-quality concrete structures form a significant part of the overall cost of nuclear energy and rely more on local suppliers than the components. Similar structures are used in hydro and wind power.
- Manufacturing control for modules: Modular construction planned to be used with SMRs is already the norm in shipbuilding. Quality assurance will be important for SMR modules, but similar innovations could be beneficial for module-based electrolyser systems.

Innovation to improve industrial competitiveness

- Inspection and maintenance in integrated high-density designs: Given the importance of small size and footprint, various SMR designs have very tightly packed components that need inspection and maintenance. Although robotics is already playing an important role, its rapid development would expand the potential use of SMRs.
- Methods to integrate suppliers into the nuclear supply chain: While Europe has a significant machine-building industry and could contribute to the supply chains of SMRs, entry into the nuclear supply chain can be difficult. Faster integration of new companies will be needed for the large-scale growth foreseen in the clean energy transition.

Opportunities in digital and AI in nuclear energy

- Utilization of AI, digital twins in complex design with systems engineering: Previously nuclear power plant designs have strongly relied on a detailed and descriptive set of requirements, often country-specific. The modern approach is more performance-based and allows innovative designs if those can be produced and analysed efficiently. AI-generated designs and digital twins – computer models of the physical world – can be used to accelerate this design process and compared to many other industries nuclear has a long history of accurately modelling the facilities.
- Efficient regulation with transparent AI for regulators and licensees: Regulatory compliance can produce huge amounts of work and documentation both for the licensee

and the regulator. This process could be done more efficiently with AI but in a transparent, traceable and justified manner. Recent work has been done in requirements analysis and similar topics are likely important for the financial and medical sectors.

- AI for predictive maintenance: Nuclear power plant maintenance can be quite conservative, as components are changed or checked according to rules on a precautionary basis. Putting the effort into the most likely components needing maintenance, could both reduce the amount of work needed and focus it on improving reliability. This has been used for instance in changing the order that pump insulations are checked.

Overall, there are various areas where innovations can accelerate the deployment of new clean energy technologies, such as SMRs, many of which are synergistic with other industries and the EU has various ways and instruments to contribute to these common goals.

A SYNTHESIS ON SMRS AND AI

Zsolt Fülöp, Chairman of the Hungarian National Research Infrastructure Committee

SMR technology is a promising development in the field of nuclear energy and AI applications are penetrating more and more innovations. Therefore the possible synergies between SMR and AI should be investigated emphasizing the European context. The main message from all stakeholders, FORATOM, SNETP and FORTUM, is similar: there is a great potential in SMR technology alone, and the AI could open a new vista to nuclear energy from design to predictive maintenance.

There is a clear demand for low carbon initiatives for advanced technologies and SMRs can be one of the important vehicles to reach the net zero aim by 2050. Europe has the research and development capabilities in nuclear technology and the SMR Partnership together with the first EU workshop on SMR in 2021 is a clear message of interest from the actors in the field. The European SMR Partnership will allow the establishment of a strong collaboration scheme involving industry stakeholders, research and technological organizations, interested customers as well as European policymakers and regulators. Beyond their technical merit, SMRs are a new business model which may represent a key enabler towards an efficient energy transition, provided they are supported by a strong effort of R&D&I and training of young staff. Taking into account the long way toward the commercial SMRs a step-wise approach is necessary considering the various aspects of development in market integration and deployment, licensing, financing and partnerships, supply chain adaptation, and innovation and R&D.

SMRs are the first nuclear products to be developed in a new digital and AI era therefore a new approach should be developed where the synergies between nuclear and AI technologies are used to boost the performance and safety of the systems. There are several aspects of the above synergies that are already identified.

AI-generated designs and digital twins, computer models of the physical world, can be used to accelerate the design process and compared to many other industries nuclear has a long history of accurately modelling the facilities.

Generating and checking documentation for regulatory compliance could be done with AI more efficiently, but only if the AI tools are transparent, traceable and justified. Nuclear power plant maintenance can be quite conservative, components are changed or checked according to rules on a precautionary basis. Using AI for predictive maintenance could both reduce the amount of work needed and focus it on improving reliability.

A detailed investigation is needed to explore further synergies between AI and SMR involving AI experts. The final aim could be to use AI even in nuclear waste management, an important aspect of nuclear energy production. Further analysis is needed to explore how cyber-security, digital twins and environmental issues be connected with the nuclear field. On the

other hand, the results of a successful AI-SMR collaboration could be transferred to other sectors by facilitating cross-sectoral synergies.

Euratom and Horizon Europe are key research programmes to boosting the SMR initiative. This can include research and training efforts, focussing on safety and emergency preparedness. Special attention should be paid to financing aspects to validate the feasibility and efficiency of SMRs from the financial point of view. The exploration of the AI contribution to the field is an example of cross-synergy which therefore needs special attention.

From the Central-Eastern European perspective, the nuclear option seems to be one of the viable solutions to reduce CO_2 emissions. The advantages of SMR technology are clear. Licensing and regulation, however, can vary from country to country, therefore a joint EU effort is needed to harmonize these processes. Moreover, the expertise of countries in nuclear research and technology can be a key element in SMR development. It is therefore, strongly suggested to reinforce collaboration, training and education efforts on nuclear technologies at European level to guarantee the development of nuclear competences and skills of young scientists and professionals which is essential for the long road towards the successful European design, construction and implementation of SMR.

STAKEHOLDER VIEWS: SNETP AND FORATOM

In light of the current developments, what research actions could further support SMRs?

SNETP, in its strategic research and innovation agenda (SRIA)[13], has identified the most important technical areas of R&D&I to allow the EU Member States wishing to build SMRs to make decisions based on sound technical and scientific evidence. The priorities that have been identified are the following:

- Safety assessment of existing concepts: Feasibility and benefit of inherent safety features (e.g. natural convection cooling and passive decay heat removal);
- Review of safety classification of components;
- Development and qualification of components (e.g. compact heat exchangers) and associated fabrication processes;
- Human factors when employing multi-module SMR plants monitored in a single control room or remotely;
- Cost reduction through Design simplification, compactness, and modularity;
- Advanced manufacturing, assembly and digitalisation of process;
- Economics and Financing (e.g. effect of in-series production on affordability, required threshold for orders, analysis of financing options);
- Site availability (water vs. air-cooling);
- Licensing (standardization and simplification);
- Acceptance of modularity aspects;
- Hybrid Energy Systems, hydrogen production, energy buffering/storage and cogeneration;
- Facilitation of demonstration of innovation to decrease time to market.

In addition to the technical and scientific challenges described in detail within the SRIA, it is also important to consider the integration of SMRs into the future low-carbon energy mix: the development of an integrated approach for the assessment of the whole energy hybrid system, composed of nuclear reactors, fossil plants, intermittent renewables energies, biomass and hydro is a huge opportunity for SMRs and the optimization of the energy mix.

[13] SNETP Strategic Research and Innovation Agenda 2021: https://snetp.eu/wp-content/uploads/2021/09/SRIA-SNETP-1.pdf. Filipe Boccato Payolla, Radiopharmaceuticals for diagnosis in nuclear medicine: a short review. Eclética Química, vol. 44, no. 3, pp. 11-19, 2019: https://doi.org/10.26850/1678-4618eqj.v44.3.2019.p11-19.

Which new SMR designs can be demonstrated in the EU by 2035-2040?

Light water SMRs are mature enough to begin to be deployed in a 10-year schedule. The R&D&I shall focus on the main technical and scientific issues (see above) related to this technology. Other advanced SMRs which are being developed within SNETP that have additional features, such as the capability to close the fuel cycle, to produce very-high temperature heat, etc., are to be deployed after the following decade. These would need further R&D effort to reach an acceptable maturity level.

What is the area where SMRs will play a significant role in achieving the EU carbon neutrality goals?

Nuclear energy is the largest dispatchable low-carbon technology non-weather dependent and is therefore already contributing to the EU's greenhouse gas emissions reduction and it will continue to do so in the long run. Both the existing fleet that needs to continue operating and the development and deployment of a new fleet of reactors, including SMRs, will ensure a carbon-free European economy. It is important to note that nuclear reactors, including SMRs, have a positive impact on the consumption of raw materials, which is low compared to other technologies, as well as have a small land-use footprint. SMRs will go beyond power production and will provide capabilities of crucial importance, for example in hydrogen production, heat production for industrial applications, district heating or desalination. Due to their technical characteristics, SMRs can bring benefits to small and remote communities for energy production, as well as industrial clusters which seek a stable and secure electricity or heat source for the development of their industrial activities.

What are the main challenges and opportunities for the deployment of AI and digitalization in the SMRs design?

The main challenge is trustworthy AI. It is a cross-cutting and cross-sectorial topic on which Europe may take the lead. It is cross-sectorial because other critical technologies such as aerospace, space and medicine, face the same issues. Therefore, a cross-sectorial action launched in the Horizon Europe Program would be highly valuable.

In which way is the EU Nuclear industry preparing an industrial supply chain for the future production of SMRs?

The main characteristic of the European nuclear supply chain is that it is local, and can support the deployment of future reactors from domestic suppliers. In this context, the nuclear industry, together with its partners from the research community, is working through the European SMR pre-partnership to identify specific needs for SMR manufacturing and designs and the potential barriers that might hinder the deployment of this technology. It is crucial for maximising new tools and methods in SMR manufacture and through-life operation, digitalisation, novel techniques. Likewise, staffing considerations for SMR design, manufacturing and operations are being analysed. It is of the utmost importance that

standardisation is achieved in SMR development and that the use of non-nuclear standard components is part of the road to the development and deployment of SMRs.

What kind of support could be provided by Euratom research actions in that frame?

Despite the limited budget within the Euratom fission research and training programme, a certain number of actions could be undertaken to:

- Promote codes and standards which take profit from European knowledge.
- Build a global supply chain, from the sub-contractors to the final customer and the re-processing of old equipment, similar to photovoltaics, batteries and hydrogen.
- Develop more innovative and cross-sectorial projects with AI, additive manufacturing, digital and research infrastructures for the demonstration, verification, and validation of new nuclear technologies to help integrate them most effectively.
- Facilitate and encourage cross-sectoral collaboration within the SET-plan on a technology-neutral basis.

What is the role of SMRs and large-scale nuclear power plants? Is there complementarity or contrast?

SMRs and large-scale nuclear power plants do not compete but complement each other. Addressed to different markets and market needs, SMRs are the nuclear sector's response to the energy market decentralisation efforts. As highlighted before, large reactors that are as of today providing 25% of electricity, and 50% of the decarbonised electricity in Europe, should continue to do so with long-term operation programs that are being put in place. Large reactors that operate for decades meet large energy demands. SMRs, as described above, will benefit small and remote communities, will provide electricity needs to specific industrial clusters, are a solution for district heating projects, and will also be used for hydrogen production. SMRs are an innovative technology that can be deployed rapidly.

MEDICAL APPLICATIONS USING NUCLEAR TECHNOLOGIES AND AI

PROMISES AND NEEDS OF NUCLEAR MEDICINE

Jolanta Kunikowska, President of the European Association of Nuclear Medicine (EANM) and Professor at the Nuclear Medicine Department of the Warsaw Medical University

Nuclear medicine is a medical specialisation that involves the administration of radioactive substances (radiopharmaceuticals) to diagnose and treat diseases in patients of every age group. Nuclear medicine contributes to the diagnostic and treatment of numerous severe diseases, including cardiological, endocrinological and neurological diseases, with a specific focus on cancer as more than 80% of all nuclear medicine procedures are related to cancer treatment[14]. Every year, more than 10 million patients in Europe benefit from nuclear medicine, with 100 different nuclear medicine procedures already approved by regulators. Radiopharmaceuticals (RPs) are used for:

- Diagnostic purposes: The RPs are injected into the patient and are detected within the body using specific technologies, such as planar gamma cameras, SPECT- (Single Photon Emission Computed Tomography) or PET- (Positron Emission Tomography) scanners. These scanners produce a highly accurate image of the processes within the individual patient. Therefore, nuclear medicine is considered to be "functional imaging" rather than "anatomical imaging" like diagnostic-focused sister modalities, such as ultrasound, magnetic resonance imaging (MRI) or computed tomography (CT). Both imaging methods are nowadays combined in multi-modality imaging scanners.
- Treatment purposes: RPs can also be used for therapeutic purposes in nuclear medicine. In this case, RPs are injected into the patient or given orally, diffuse in the body, and attack specifically the diseased (cancer) cells in a highly targeted approach, significantly limiting damage to healthy tissue as compared to e.g. external radiotherapy.

Theranostic approach

The European Association of Nuclear Medicine (EANM)[15] is proud of the tremendous innovations in the field of nuclear medicine in general and in the advancement of radiopharmaceuticals specifically. These developments have substantially improved patient care, especially in oncology globally and have their roots in Europe. The evolution of new Radiopharmaceuticals have paved the way for a new paradigm in patient care and

[14] Filipe Boccato Payolla, Radiopharmaceuticals for diagnosis in nuclear medicine: a short review. Eclética Química, vol. 44, no. 3, pp. 11-19, 2019: https://doi.org/10.26850/1678-4618eqj.v44.3.2019.p11-19.
[15] The European Association of Nuclear Medicine (EANM): https://www.eanm.org/.

personalised medicine, opening new opportunities in basic research and underpinning the potential and value of nuclear medicine.

Indeed, nuclear medicine holds a lot of promises for the future. Europe being a world leader in nuclear medicine, various cutting-edge radiopharmaceuticals and pioneering and exciting new uses are under development.

The innovations and promises of nuclear medicine can be exemplified by the 'theranostic' approach. The combination of diagnostic with therapeutic radionuclides is referred to as the theranostic approach. Theranostics in nuclear medicine means using the same chemical structure for radiopharmaceuticals to both diagnose and treat disease. It is considered the gold standard of personalised medicine and has paved the way for targeted care of particularly oncological patients. While the theranostic approach has been successfully applied by nuclear medicine physicians for decades in the treatment of thyroid disease already, recent innovations in the field of radiopharmaceuticals have helped to expand its application to other tumour entities such as neuroendocrine tumours and prostate cancer.

An example is the radionuclide lutetium 177 (^{177}Lu). The use of theranostics in nuclear medicine to treat neuroendocrine tumours reflects the life-changing impact that nuclear medicine can have on patients. A neuroendocrine tumour is a second tumour from the gastrointestinal tract, which can develop in many different organs. It characterizes the overexpression of different receptors. One of the most common is the somatostatin receptor which is based on specific a receptor-targeted therapy with ^{177}Lu, called [^{177}Lu]Lu-DOTA-TATE. This innovative radiopharmaceutical has shown very positive results, improving both survival parameters and quality of life. The NETTER-1 trial has shown a 79% reduction in the risk of disease progression and death.[16] ^{177}Lu is also used to treat prostate cancer patients for which another target is used, prostate specific antigen (PSMA) in the form of [^{177}Lu]-PSMA-617. Prostate cancer is the second most frequent cancer diagnosis made in men and the fifth leading cause of death worldwide. Recently published results of the VISION Trial in progressive castrate resistance prostate cancer patients showed a 38% reduction of death and a 60% reduction in risk of progression for patients treated with this Radiopharmaceutical[17]: this is innovation in action.

Research needed on equipment and radiopharmaceuticals

This tremendous innovation has improved the lives of thousands of patients. However, what has been achieved to date is not comparable to what could be achieved in the next ten years, provided that more research funding is made available. Indeed, because such procedures are very expensive and require dedicated facilities, this is not yet equally accessible in Europe

[16] Strosberg J, El-Haddad G, Wolin E, et al. Phase 3 trial of ^{77}Lu-dotatate for midgut neuroendocrine tumors. N Engl J Med 2017; 376: 125–35. Sartor O, de Bono J, Chi KN, et al. Lutetium-177-PSMA-617 for metastatic castration-resistant prostate cancer. N Engl J Med 2021; 385: 1091–103.

[17] Sartor O, de Bono J, Chi KN, et al. Lutetium-177-PSMA-617 for metastatic castration-resistant prostate cancer. N Engl J Med 2021; 385: 1091–103. Nadig, V., Herrmann, K., Mottaghy, F.M. et al. Hybrid total-body pet scanners—current status and future perspectives. Eur J Nucl Med Mol Imaging 49, 445–459 (2022). https://doi.org/10.1007/s00259-021-05536-4

for cancer patients. To build on this achievement, the necessary infrastructures, e.g. for radiopharmaceuticals, therapy beds, radiopharmacy, as well as funds are required.

Because nuclear medicine's procedures are based on molecular imaging, i.e. the visualization of physiological processes in the body, the key drivers for nuclear medicine are research, innovation and education. To better diagnose and treat patients, both innovative radiopharmaceuticals and new equipment are needed.

New research area on equipment: The latest digital whole-body PET scanner[18] (the medical device used for positron emission tomography) provides an image within less than one minute while the standard PET scanners need 20 minutes. Rapid image production not only improves the patients' quality of life but also allows dynamic imaging of the tracer distribution in the body, opening up the possibility for research and development of novel drugs. However, the latest whole-body PET scanners are 5-times more expansive than standard PET scanners, explaining why this life-changing technology is still not widespread across Europe.

New research area on radiopharmaceuticals: The advancements in molecular biology, radiochemistry and radiopharmacy in recent years have changed the possibilities for production, preparation and use of Radiopharmaceuticals in diagnosis and treatment. For diagnosis procedures to be as precise as possible and for treatment options to be as targeted as possible, novel and innovative radiopharmaceuticals are always needed, therefore requiring new isotopes and new targets. While this was a low priority at the European level for a long period, this has progressively changed with new European research projects supporting the development of new couples radionuclides and new tumour specific biomarkers. Several projects under Horizon Europe, including MEDICIS-Promed and PRISMAP are facilitating this research.

Radioisotope shortage, accessibility to new treatments, skills and personalized medicine

The European Association of Nuclear Medicine (EANM) is looking forward to exploring potential opportunities to address research and innovation needs in the European context to ensure that innovation reaches all patients across Europe in the coming years. The development of innovative diagnosis and therapy procedures, while ensuring the stable and resilient supply of radioisotopes and quality and safety for EU patients, is the main priority of EANM when it comes to research and innovation.

In the past years, EANM has been pleased by the increasing commitment of the European institutions towards medical applications through the Euratom Research and Training programme including research on applications and supply of radionuclides for therapy, the European Partnership on Radiation protection and medical applications as well as the revamped Education and Training in nuclear science and technologies.

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[18] Nadig, V., Herrmann, K., Mottaghy, F.M. et al. Hybrid total-body pet scanners—current status and future perspectives. Eur J Nucl Med Mol Imaging 49, 445–459 (2022). https://doi.org/10.1007/s00259-021-05536-4.

The elements below cover current research and innovation needs that could be included in future European research projects.

- **Radioisotope shortage:** The nuclear medicine community is very concerned by potential radioisotopes shortages, potentially disrupting healthcare delivery. This can be explained by the ageing of most European research reactors, producing the necessary radioisotopes: most of them have an end of operation date before 2030 and new projects are facing numerous challenges. Significant investment is required to increase and strengthen European capacity in this regard, but new research reactors will bring opportunities for efficiency and sustainability gains. The EANM is therefore calling for further investment in new research reactors and active support for technological innovation in the radioisotopes supply chains (Euratom, EU Structural Funds).
- **Equipment:** Acessibility to new treatments and techniques: Important inequalities across the European Union in terms of nuclear medicine equipment are persisting, especially in European periphery countries where necessary facilities are lacking. The EANM is therefore calling for support for research and innovation for the development and dissemination of state-of-the-art infrastructures and equipment for high-quality care across Europe, such as whole-body PET scanners and long field view PET (EU4Health, Cohesion Funds, Invest EU programme).
- **Skilled workforce:** Recent technological and radiopharmaceutical developments have contributed to tremendous progress in the field of nuclear medicine, creating the need for changes in nuclear medicine training programs. In addition, an adequately sized and well-trained workforce is essential to bring nuclear medicine to the patients and to ensure the safe and correct implementation of radioactivity-based procedures. However, the education and training standards of nuclear medicine specialists in Europe are extremely heterogeneous. The EANM believes that focusing on the younger generation is of the utmost importance, through the improvement of nuclear medicine education and training standards (EU4Health, ERASMUS+).
- **Road to personalized medicine:** The nuclear medicine field has tremendous potential for innovation in the coming years both through the use of theranostics for new applications and the development of new agents specifically targeting molecular structures on pathogenic cells. Whether the nuclear medicine field will be able to deliver on its promises will mainly depend on European support for the development of new radiopharmaceuticals, new targets and a new couple of radioisotopes through specific funding and programmes (Horizon Europe, Euratom).
- **Long-term risk from low dose, internal dosimetry, quality assurance:** Standardized and traceable activity quantification as well patient-tailored treatment are currently improving the safety of treatments. To further optimize outcomes and procedures for patients, the EANM would welcome roadmaps to standardization, traceability of results and support to radiobiology for radionuclide applications through Euratom. The EMPIR-

MRTDosimetry project [19] is an impactful example of what can be achieved when pooling expertise.

Nuclear medicine's policy priorities

R&I are essential pillars of nuclear medicine development. However, this needs to be accompanied by a supportive legal framework. While Europe has a long and strong tradition in nuclear medicine, being home to the biggest radiopharmaceutical companies and benefiting from strong academic and medical centres, Nuclear Medicine is still facing a lot of challenges, related to:

- The lack of harmonised high-quality standards for the education of healthcare professionals on the delivery of high-quality nuclear medicine services and unharmonized training curricula throughout Europe.
- Insufficient healthcare infrastructure to accommodate nuclear medicine facilities, in terms of medical equipment, configurations of supply chains and ageing research reactors producing medical isotopes.
- Non-optimal regulatory frameworks do not consider the specificities of the sector.

In this respect, EANM is committed to ensuring that all patients in Europe have equal access to high-quality nuclear medicine services. This should be achieved by:

- Achieving full recognition of nuclear medicine as a core individual medical specialty by all national and international stakeholders and institutions.
- Upholding and advancing a common high standard of nuclear medicine specialists' education and training in all European countries.
- Creating a supportive regulatory environment for nuclear medicine, that recognises the specific characteristics of the field and is well adapted to realities and future requirements.
- Ensuring that health systems have in place robust and sustainable supply chains and state of the art infrastructure to guarantee sustained contribution of nuclear medicine to patient care.

Europe's Beating Cancer Plan and the SAMIRA Action Plan, once implemented, will act as impactful tools for supporting nuclear medicine.

Highlighting the current research and innovation needs and priorities for nuclear medicine sheds the light on the necessary synergies between the health and energy sectors and demonstrates how the Euratom programme, in conjunction with other EU programmes and policies, can help to bring nuclear medicine innovation to patients.

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[19] The EMPIR-MRTDosimetry project: https://www.euramet.org/research-innovation/search-research-projects/details/project/metrology-for-clinical-implementation-of-dosimetry-in-molecular-radiotherapy/?L=0&tx_eurametctcp_project%5Baction%5D=show&tx_eurametctcp_project%5Bcontroller%5D=Project&cHash=7c3aac558f1cc6dcb19147b7dab4e423.

MEDICAL APPLICATIONS USING IONISING RADIATION

Hildegarde Vandenhove, President of the European Radiation Protection Research Platforms (MEENAS) and Director of the Environment Health and Safety Institute (SCK CEN)

MEENAS,[20] the Consortium of European radiation protection research platforms was established in March 2020 as the umbrella organisation of the six European research platforms, MELODI for low dose effects of radiation, EURADOS for dosimetry, EURAMED on radiation protection in medical applications, NERIS for emergency management and response, ALLIANCE for radioecology and SHARE for social sciences. MEENAS represents virtually the complete European radiation protection research community. The aim of MEENAS is a.o. to promote European radiation protection research, develop and implement the joint roadmap and associated research and innovation needs, including in medical applications.

Radiation protection, right from the beginning in medical applications

Applications of ionising radiation and radionuclides in diagnostic, interventional and therapeutic procedures in medicine are beneficial for hundreds of millions of people each year. Radiological protection ensures justification and optimisation of medical applications and balances the expected benefit of the use of ionising radiation for the patient with the protection of their health from harmful effects of ionising radiation. The importance of radiation protection is clear if we evaluate the results of the European EPI-CT project that carried out a Europe-wide epidemiological study to quantify risks for paediatric computerized tomography. The project showed a significant dose-response relationship for these children amongst others for brain cancer and leukaemia. The importance of radiation protection in medical applications is obvious: it allows optimising the benefit/risk ratio for medical use of ionising radiation including the possibility of personalised medicine since every person reacts differently to radiation.

MEENAS proposes to focus collectively research and innovation on radiation protection in medical applications in the domains below and suggests that attention and budget are dedicated to medical applications via the DG R&I Euratom Program calls, or via associated DG SANTE calls.

The optimisation of existing clinical applications and the development of new applications using ionising radiation must be driven by clinical needs and radiation protection must be considered right from the beginning. Applications and their optimisation are disease dependent and we will focus primarily on the detection and safe treatment of cancer, but also the use of ionising radiation in the detection and treatment of other diseases such as neurovascular and cardiovascular diseases, which are the main cause of death in Europe. For interventional procedures, fluoroscopy- and CT based approaches, particle-based

[20] MEENAS, the Consortium of European radiation protection research platforms: https://eu-meenas.net/doku.php.

therapies and targeted therapies in nuclear medicine, patient treatment and patient protection require improved dosimetry procedures for individual patients and an improved dose-effect relationship for target tissue and healthy tissue. A stronger patient-centred approach is also necessary for research, development and implementation processes.

Innovation in Medical Imaging and AI

Tailoring the therapeutic strategy for personalised medicine requires innovation in medical imaging and associated dosimetry. Improvement of diagnostic techniques using AI and new knowledge on individual patient response to the exposure is needed. The establishment of dose-effect relationships for health effects and the search for radioprotectants are also crucial for optimal protection. Radiation safety is of concern for patients, their families and medical staff. There are many potential optimisation strategies for staff, including new technologies for measuring exposures and artificial intelligence based simulation technologies. The staff could also be better protected using optimised procedures, especially in interventional radiology.

Rapid advances in the development of medical applications, complex treatments, and large databases require the development of AI and computer-based decision support systems. AI and machine learning based approaches create opportunities for optimised use of radiation and such approaches should be developed in close interaction with expert organisations, such as EUR-AI.

Ethics and Patient Data

Ethical challenges linked with the use of big data and AI need to be addressed, along with data sharing, data quality, storage and processing matters (European Health Data Space). AI technologies need to be quality assured, requiring application-specific AI expertise and technology to verify and validate AI products for clinical use. On the other hand, for knowledge to progress, more swift access and use of patient data are required and European policy may need to be changed in accordance with the Scandinavian approach. Quality control of provided data and continuous post-AI implementation monitoring for unintended consequences should be introduced.

Another important area is assessing and addressing barriers to the transfer of developments into clinical practice and minimising differences throughout Europe. Standards should be defined for the justification of applications depending on patient characteristics and benefit-risk evaluations of procedures guaranteeing the best possible radiation protection for patients and staff everywhere in Europe. The results of the research and innovation activities will support the implementation of the European Basic Safety Standards, to manage new requirements and harmonise the practices and various regulations (Euratom and DG SANTE) throughout Europe.

Education and Training (E&T) of health professionals and scientists to maintain and build capacity and ensure sustainability in the field are essential. How to organise, harmonise, implement and disseminate evidence-based E&T in medical radiation protection, to ensure training linked to novel medical applications, is a major challenge.

The European Partnership for research in radiation protection

MEENAS strongly welcomes the Euratom European Partnership for research in radiation protection and detection of ionising radiation (PIANOFORTE) which will serve as a foundation for helping to ensure the achievement of the set goals and interlinking medical radiation protection with other research programmes is important. This will be done considering the outcomes of the Euratom projects EURAMED rocc-n-roll, MEDIRAD, SINFONIA and HARMONIC projects but also in consultation and interaction with amongst others Europe's Beating Cancer Plan, the SAMIRA initiative and DG SANTE.

Euratom and the radiation protection community invited the medical sector because of the important contribution (more than 50 %) of medical applications using ionising radiation in diagnostics and therapy to the overall average radiation dose to the public (much higher contribution for individual patients and medical personnel), which is only increasing. On the other hand, there are virtually no programmes or calls under the European Commission health programmes on medical applications of ionising radiation where radiation protection aspects are considered despite the significantly higher available budgets in these health programmes. Yet this Europe-wide multidisciplinary cooperation in radiation protection is critical to assure the public, including patient and medical personnel, health and welfare.

AI AND HIGH-PERFORMANCE COMPUTING IMPROVING NUCLEAR MEDICINE

Margarita Kirienko, Research Physician at the Nuclear Medicine Department of the National Cancer Institute in Milan

Medical imaging is moving toward automated systems and approaches capable of assisting and supporting medical decisions. Recently, nuclear medicine has experienced a growing interest in AI-based applications as well since significant improvements are expected from AI technology for both nuclear medicine purposes: diagnostic and therapeutic. As for diagnostic applications, AI-based algorithms have been proposed for a wide range of technical and clinical objectives. Indeed, machine learning algorithms have been demonstrated to be of value for image quality improvement and automatic extraction of a higher amount of information from raw and processed images. Clinical applications comprise lesion detection, diagnosis, and prognostication in oncology, neurology and cardiology.[21] As for therapeutic applications, AI tools are under investigation aiming at improving patient-specific dosimetry calculations, exploit diagnostic and therapeutic molecular images to derive biomarkers for treatment efficacy and outcome prediction.[22]

AI and high-performance computing are expected in the near future to accelerate and open new opportunities in research and then in daily practice in nuclear medicine. Indeed, they have the potential to improve workflow and productivity in imaging applications by improving the imaging chain from patient scheduling, patient setup, protocoling, data acquisition, detector signal processing, reconstruction, image processing and interpretation.[23] Moreover, AI technology may enhance clinical and research capabilities by innovative drug design, and identification of imaging biomarkers. Additionally, molecular imaging may enable robotic precision surgery by means of AI, augmented reality, and navigation.[24]

AI methods are expected to accelerate therapeutic drug design, support radiobiology research, and personalize radiopharmaceutical therapies. The main challenges that the community is facing in AI development may be classified in general issues shared with fields other than healthcare, issues shared within health-related fields, and issues that are nuclear medicine-specific.

Challenges in AI development shared with other fields than healthcare

Firstly, one of the main barriers to AI-based algorithms development is the scarcity of datasets. Large, diverse datasets are crucial for success. A potential drawback of AI prediction is its dependence on the data being used to train the algorithm. Training data have to represent the diseases and patient populations under evaluation and be balanced to

[21] Nensa F, Demircioglu A, Rischpler C. Artificial Intelligence in Nuclear Medicine. J Nucl Med. 2019;60:29S-37S.
[22] Brosch-Lenz J, Yousefirizi F, Zukotynski K, Beauregard J-M, Gaudet V, Saboury B, et al. Role of Artificial Intelligence in Theranostics:: Toward Routine Personalized Radiopharmaceutical Therapies. PET Clin. PET Clin; 2021;16:627–41.
[23] Sitek A, Ahn S, Asma E, Chandler A, Ihsani A, Prevrhal S, et al. Artificial Intelligence in PET: An Industry Perspective. PET Clin. PET Clin; 2021;16:483–92.
[24] Wendler T, van Leeuwen FWB, Navab N, van Oosterom MN. How molecular imaging will enable robotic precision surgery : The role of artificial intelligence, augmented reality, and navigation. Eur J Nucl Med Mol Imaging; 2021;48:4201–24

perform correctly when exposed to diverse patient data.[25] However, large and representative patient cohorts are challenging to enrol because of ethical limitations, expense, time requirements, or suboptimal ground truth.[26] Additionally, data need to be structured to allow immediate processing by AI algorithms. Nowadays, electronic health records are moving toward harmonization while medical imaging is less standardized. Moreover, for diagnosis and prognostication, the AI algorithms' training is performed in a supervised fashion. Consequently, for model development, data need to be annotated by experts, which is a tedious, costly and time-consuming task. To address these challenges, several initiatives from scientific societies, including EANM, for data harmonization are ongoing for years. Project-specific databases have been created within research consortia. The availability of such public datasets for a wide range of conditions could accelerate the research path. Particularly, the European Health Data Space will facilitate non-discriminatory access to health data and the training of artificial intelligence algorithms on those datasets, in a privacy-preserving, secure, timely, transparent, and trustworthy manner, and with appropriate institutional governance. European funding opportunities have been put in action within Horizon Europe programs to face data-related issues, consequently, positive outcomes are expected in the years to come. However, some health-specific data-related challenges still need to be addressed.

Secondly, AI-based tools are challenged by the proof of their reliability which is related to methodological aspects and explainability. Algorithms' architecture, high-quality training information, adequate assessment of outcomes, endpoints, events, real-world validation, comprehensive results' publication constitute the basis for a robust model.[27] However, research is needed to dissect the optimal model design for each purpose; to understand the best hardware-software architecture; to address the issue of underspecification, which occurs when many distinct solutions can solve the problem equivalently.[28] All these steps would benefit from high-performance computing and meticulous transparency on data and methods. The so-called eXplainable AI (XAI) field is growing, with the aim to develop responsible AI and encourage experts and professionals to embrace the new technology's benefits.[29] Open Science is gaining wide acceptance in the scientific community, while balancing between industry, legal and health aspects requires dedicated attention and work.[30]

Another pre-requisite for AI tools' development and implementation is the digital infrastructure that could support information exchange among healthcare institutions, clinics, and citizens.

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[25] Bi WL, Hosny A, Schabath MB, Giger ML, Birkbak NJ, Mehrtash A, et al. Artificial intelligence in cancer imaging: Clinical challenges and applications. CA Cancer J Clin; 2019;69:127–57.
[26] Minssen T, Rajam N, Bogers M. Clinical trial data transparency and GDPR compliance: Implications for data sharing and open innovation. Sci Public Policy. 2020.
[27] Erickson BJ. Deep Learning and Machine Learning in Imaging: Basic Principles. Artif Intell Med Imaging. Cham: Springer International Publishing; 2019. p. 39–46.
[28] D'Amour A, Heller K, Moldovan D, Adlam B, Alipanahi B, Beutel A, et al. Underspecification Presents Challenges for Credibility in Modern Machine Learning. 2020.
[29] Barredo Arrieta A, Díaz-Rodríguez N, Del Ser J, Bennetot A, Tabik S, Barbado A, et al. Explainable Artificial Intelligence (XAI): Concepts, taxonomies, opportunities and challenges toward responsible AI. Inf Fusion. Elsevier; 2020;58:82–115.
[30] Ross-Hellauer T, Reichmann S, Cole NL, Fessl A, Klebel T, Pontika N. Dynamics of cumulative advantage and threats to equity in open science: a scoping review. R Soc open Sci; 2022;9:211032.

Technical challenges consist of computational burden and the communication overload that need to meet the infrastructure constraints. In this regard, the number of nodes and kinds of data distributed among nodes are crucial hyper-parameters that need to be tuned. Distributed architecture for AI-based algorithms is an effective strategy for multi-institutional collaboration with the potential advantage of being privacy-preserving. Some commercial and open source solutions have recently become available, supporting the feasibility of implementing a distributed learning infrastructure.[31,32] Some funding opportunities within the Horizon Europe program have been open and will be available in the upcoming years. However, dedicated medical (imaging)-data initiatives are needed.

The approval process by the European Medicines Agency (EMA) and member state regulators of AI-based tools requires a dedicated strategy. The European Commission has introduced a legislative proposal for a Regulation on Artificial Intelligence (Artificial Intelligence Act) with harmonised rules for the development, placement on the market and use of AI systems in the EU. Regulatory considerations on Bioinformatics, Algorithms, Machine Learning and AI have been outlined in the HMA-EMA Joint Big Data Taskforce Phase II report: 'Evolving Data-Driven Regulation'. A robust regulatory framework will allow a straightforward development path.

Challenges in AI development shared with health-related fields

Among the challenges shared among different medical specialties, legal issues require the integration of AI systems into the doctor-patient relationship, a field where liability has always been set between human actors, which is expected to complicate the attribution of responsibility. A dedicated legal background involving AI and AI-related technologies is under discussion. The Committee of Legal Affairs of the European Parliament presented a 'Report with recommendations to the Commission on a civil liability regime for AI', which highlighted that legal challenges posed by the development of AI systems have to be addressed taking into consideration both the protection of the public and business incentives to invest in AI innovation.

Despite a growing interest in AI ethics, implementing AI-related technologies and initiatives responsibly in healthcare settings is a challenge.[33] AI technology developers and providers should aim at ethical, transparent, and accountable AI solutions. This ethical consideration of AI would help healthcare providers maintain trust in AI tools and healthcare organizations to maintain trust between caregivers and patients. Research is needed to understand the practices, mechanisms, and ecosystems that facilitate responsible AI use in healthcare.

The important question is how to bring AI into the clinical workflow in an efficient and scalable way. An effective approach to the deployment of AI in clinical environments is unclear. It is

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[31] Kirienko M, Sollini M, Ninatti G, Loiacono D, Giacomello E, Gozzi N, et al. Distributed learning: a reliable privacy-preserving strategy to change multicenter collaborations using AI. Eur J Nucl Med Mol Imaging; 2021;48:3791–804.
[32] Zerka F, Barakat S, Walsh S, Bogowicz M, Leijenaar RTH, Jochems A, et al. Systematic Review of Privacy-Preserving Distributed Machine Learning From Federated Databases in Health Care. JCO Clin cancer informatics; 2020;4:184–200.
[33] Siala H, Wang Y. SHIFTing artificial intelligence to be responsible in healthcare: A systematic review. Soc Sci Med. Pergamon; 2022;296:114782.

expected that in the near future, hundreds of AI algorithms for use in clinics and operating on different steps of clinical workflow and data will be approved. If we depend on each AI vendor to use their own methods, the deployment and growth of AI in clinical practice could stall as the complexity would quickly become unmanageable. Innovative solutions for data and algorithms ecosystems are warranted. The availability of data in new ecosystems would open opportunities for processing, training new AI algorithms, deriving AI inferences, and validating continuously the models.[23]

The providers should be able to ensure the bias monitoring, its detection and correction concerning high-risk AI systems. Health professionals should be "in the loop" in terms of responsibility and development. Consequently, training on methodologies and education on ethical deployment is mandatory. Currently, knowledge of AI is limited for non-computer scientists and further education is desired. Many stakeholders expressed the need for collaboration between healthcare providers and AI specialists to successfully improve clinical adoption and patient care. Indeed, limited AI-specific knowledge levels among professionals are associated with fear, while intermediate to advanced AI-specific knowledge levels are associated with a positive attitude towards AI. Additional training may therefore improve development and implementation. Dissemination of knowledge for the public will contribute to a trustful and critical appraisal of AI technology.

Challenges in AI development specific to *nuclear medicine*

Coming to the nuclear medicine specific challenges, we must highlight the core of this medical specialty, which is the use of radiopharmaceuticals. AI offers the potential to transform drug development. In recent years, AI-based drug discovery has grown substantially using neural networks to design molecules, and the application of knowledge graphs contributed to understanding target biology. Several molecules progressed into clinical trials, in some cases with greatly accelerated timelines and reduced costs. Pharmaceutical companies have formed partnerships with AI companies to explore the discovery technology. Radiopharmaceutical development may benefit from this trend. The additional challenge is the radioactive nature of the molecules. On one hand, research needs to be supported by the radionuclide supply. On the other hand, AI-based modelling may prevent developers from radioactive exposure. Currently, it is still early days for AI in radiopharmaceuticals' discovery. AI holds the potential to create value in drug discovery, by means of greater productivity, wider molecular diversity and enhanced chances of clinical success.[34]

Radiopharmaceutical imaging allows non-invasive, repeatable, whole-body assessment, and allows the calculation of quantitative parameters that, therefore, can provide image-derived biomarkers of biological processes, protein and receptor expression, in-vivo organ function. Biomarkers of disease severity and potential resistance to treatments would be of fundamental importance to inform treatment decisions, avoid potentially toxic and ineffective

[34] Jayatunga MKP, Xie W, Ruder L, Schulze U, Meier C. AI in small-molecule drug discovery: a coming wave? Nat Rev Drug Discov; 2022.

therapies, target aggressive diseases and develop patient-tailored therapeutic approaches. AI technologies have been demonstrated to successfully process the images with a variety of applications (segmentation, detection, diagnosis, heterogeneity assessment). Consequently, AI-based tools are expected to accelerate further biomarkers discovery, with the potential to integrate multidimensional data.[35]

Radiobiology studies the interactions of ionizing radiation on atomic and molecular structures and consequently their induced effects on cells, tissues, and organs, both normal and diseased. Recently, a considerable number of novel radiopharmaceuticals for diagnostic and therapeutic applications have been proposed. However, there is a need for the generation and application of more radiobiological knowledge. Systemic radiation delivery via radiopharmaceuticals is inherently different from irradiation by external radiation sources that occur in radiotherapy. Consequently, distinct radiation-induced biological responses are expected depending on the target, the ligand, and the radionuclide. This field is expected to benefit from AI technology and high-performance computing to advance knowledge, identify novel biomarkers and improve radioligand applications. Patient-specific and tumour-specific radiation sensitivity, dose-effect relationships, spatio-temporal properties, therapy response, normal tissue effects, the role of microenvironment and systemic reactions, combination therapies must be investigated; the radiobiological information needs to be considered together with physical and medical parameters in the development of nuclear medicine procedures[36,37] .AI-based methods will allow to derive biomarkers for absorbed dose and outcome prediction.

Nuclear medicine development requires structural and instrumentation updates. AI-enabled technology could accelerate research and improve clinical practice in an environment where increased data collection, increased patient flow (related to the amplified availability of diagnostic probes and therapeutic agents), and the exponentially higher amount and new imaging information (that could be derived from long-field-of-view scanners) are expected. Particularly, the increased sensitivity of the total-body scanners paves the way for short-lasting, low-dose, and dynamic whole-body imaging as well as new examination methods in almost all areas of imaging.[38] In Europe diffuse availability of nuclear medicine wards and high-end imaging equipment, enhanced by AI-based tools, will contribute to position European nuclear medicine as a world leader.

In conclusion, artificial intelligence will enable nuclear medicine advanced diagnostics, personalised and targeted therapies that require

[35] Castiglioni I, Rundo L, Codari M, Di Leo G, Salvatore C, Interlenghi M, et al. AI applications to medical images: From machine learning to deep learning. Phys Med; 2021;83:9–24.
[36] Aerts A, Eberlein U, Holm S, Hustinx R, Konijnenberg M, Strigari L, et al. EANM position paper on the role of radiobiology in nuclear medicine. Eur J Nucl Med Mol Imaging; 2021;48:3365–77.
[37] Vinnikov VA, Belyakov O. Radiation Exposure Biomarkers in the Practice of Medical Radiology: Cooperative Research and the Role of the International Atomic Energy Agency (IAEA) Biodosimetry/Radiobiology Laboratory. Health Phys. 2020;119:83–94.
[38] Nadig V, Herrmann K, Mottaghy FM, Schulz V. Hybrid total-body pet scanners-current status and future perspectives. Eur J Nucl Med Mol Imaging; 2022;49:445–59.

- High data quality and high-performance processing capabilities.
- Digital infrastructure for data storage and sharing, and AI technology implementation into clinical practice.
- Basic radiopharmaceutical research on drug discovery, radiobiology and dosimetry.
- Education, which is the essential prerequisite to a human-in-the-loop responsible and ethical development and adoption.
- A framework that includes legal, industry, health, and citizens' perspective to integrate research and economic priorities.

AI is expected to bring disruptive research and breakthrough innovations to nuclear medicine that will position Europe as a leader in research and innovation.

A SYNTHESIS ON MEDICAL APPLICATIONS AND AI

Sonya Sergieva, Professor and Head of Department of Nuclear Medicine, Sofia Cancer Centre

Every year more than 10 million patients benefit from nuclear medicine in the diagnosis and treatment of various illnesses, as the stakeholders from EANM and MEENAS have mentioned. Diagnostic and therapeutic nuclear medicine is developing rapidly, especially in oncology. Theranostics is currently nuclear medicine approach for personalized therapy in patients with cancer. Theranostics (therapeutics and diagnostics) is a specific diagnostic procedure. It targets effective treatment after clinical application of the same target molecule, radiolabelled with different radionuclides in various tumours such as prostate cancer, NET, thyroid cancer etc. Specific target molecules are labelled with gamma/positron emitters for diagnostic or with beta/alpha emitters for therapeutic purposes.

Development of innovative routes of safety and effective clinical application of new radiopharmaceuticals for early diagnosis, treatment and palliative care in the EU includes:

- Investment and support of small modulator reactors (SMRs), new generators and alternative methods, including accelerator-based methods, as well as separation and purification methods, waste management options, nuclear security.
- Investment and development of state-of-the-art infrastructures and equipment for high-quality care, especially in Central-Eastern Europe.
- Financial assistance to introduce innovative technologies for diagnostics and therapy in nuclear medicine.
- Development of recommendations for implementing clinical trials, new biological molecules and radionuclides in clinical use with full compliance of individual and specific organ dosimetry and radiation protection measures for patients, medical staff and the public. It is extremely important for Central/Eastern Europe countries.
- To focus on education and clinical training of young specialists working in the field of nuclear medicine, reinforcing training through research in the field of radiopharmacy and radiation protection, encouraging continuous training and career upgrades, facilitating access to research infrastructure and promoting the integration of data, FAIRification processes (Findable, Accessible, Interoperable and Reusable).
- It is necessary also to take into account the Euratom Scientific and Technical Committee's opinion on the research roadmap, the SAMIRA initiative50 and the outcomes of other relevant, forward-looking analyses like the EURAMED research roadmap for medical applications, and of societal priorities, individual dosimetry and artificial intelligence deciding the exposure optimization and of societal priorities.

- AI– based technologies have great potential to improve personalized nuclear medicine and clinical work by delivering better: drug design; automated image interpretation; imaging biomarkers; personalized treatment planning; personalized therapy dosimetry.

STAKEHOLDER VIEWS: EANM AND MEENAS

What cross-cutting R&I actions are needed to maximise the societal benefits of nuclear and radiation technologies across Europe?

In order to maximise the social benefits of nuclear medicine and ensure that nuclear medicine services are equally accessible across Europe, the EU should support targeted actions for healthcare infrastructure renewal and maintenance. In the context of Europe's Beating Cancer Plan and the upcoming development of a European network of Comprehensive Cancer Centres (CCCs) which should aim at facilitating the uptake of high-quality diagnosis and treatment and reduce inequalities across Europe, the EU should take into consideration the need to include a functioning nuclear medicine department in each Member States to ensure the availability of state-of-the-art equipment. In addition, Cohesion Funds are a crucial instrument to tackle the inequalities in hospital infrastructures: funding schemes have the potential to reinforce the hospital readiness for nuclear medicine innovative procedures. In this respect, Cohesion Funds (European Social Funds and European Regional Development fund) have an essential role to play to strengthen Nuclear Medicine capacity in Europe and eliminate inequalities of access.

What are the challenges related to the quality and safety of medical applications of nuclear and radiation technologies?

All nuclear medicine applications have an excellent safety profile. Indeed, due to the extreme sensitivity of the scanners and the high efficiency of radionuclides, radiopharmaceuticals are applied in trace amounts, only once or a few times in a patient's lifetime and are always administered in a controlled environment by a nuclear medicine physician. As stated in the European Directive on Basic Safety Standards, the physician always needs to justify its use and remains fully responsible for the procedure. In addition, the safety profile of any procedure is evaluated during the preclinical and clinical trials. To avoid any human mistake during normal clinical practice, continuing professional development and exchange of best practices are key.

How can the impact of new options of diagnosis and treatment be assessed on the standard of care? What are the barriers to the introduction of new treatments?

There are important differences between Eastern and Western European countries in terms of access to new options of diagnosis and treatment, ultimately limiting standards of care in some European countries. The main barriers to the introduction of new procedures equally across the European Union are infrastructures and reimbursement schemes. For example, whole-body PET Scans, the latest innovation in terms of nuclear medicine diagnosis, and even standard PET equipment, are not equally accessible across Europe. This might be explained in part by reimbursement strategies, as these technologies are very expensive. Indeed, reimbursement and pricing strategies for radiopharmaceuticals in Europe vary

significantly among the Member States. Further studies on appropriate reimbursement as well as European guidelines on reimbursement schemes for radiopharmaceuticals are to be welcomed to ensure that all European citizens can easily access nuclear medicine lifesaving procedures.

How to strengthen skills and attract the younger generation in using diagnostics and treatments with nuclear technologies while caring about patients' safety?

An adequately sized and well-trained workforce is essential to bring nuclear medicine to the patients and to ensure the safe and correct implementation of radioactivity-based procedures. This is one of the top priorities for the European Association of Nuclear Medicine (EANM), through the European School of Multimodality Imaging and Therapy (ESMIT). The ESMIT initiative represents the EANM's response to huge changes in the educational needs of the nuclear medicine community and the rising demand for greater multimodality content. Nuclear medicine is a multidisciplinary medical specialty that not only requires a broad level of knowledge in various but also a well-educated team of specialists comprising physicians, medical physics experts, and radiopharmacists who are involved in the optimal delivery of Nuclear medicine services to patients. In addition, as the nuclear medicine specialty is highly based on technological advances and is, therefore, a rapidly evolving specialty, current knowledge is likely to become outdated in the next few years. Hence, lifelong training is of the utmost importance. ESMIT is aiming at fulfilling this need.

How can the secure and timely supply of medical radioisotopes and fight against access inequalities be insured?

The European Association of Nuclear Medicine is committed to ensuring that all patients in Europe have equal access to high-quality nuclear medicine services in Europe. Unfortunately, nuclear medicine still faces several cross-sectoral barriers, leading to inequalities of access to nuclear medicine facilities, including:

- Challenges in healthcare infrastructure, including unadapted healthcare systems and hospital infrastructure necessary to deliver nuclear medicine services to the patients.
- Regulatory challenges, including limited market access and unfavourable reimbursement and pricing strategies for Radiopharmaceuticals.

To fight these access inequalities, healthcare infrastructures should be built, renewed, or maintained, for all European patients to have equal access to dedicated centres with nuclear medicine facilities. The increase in hospital readiness for the delivery of nuclear medicine services is fundamental for scaling up their full treatment potential. In addition, the harmonisation of market access conditions and reimbursement strategies for radiopharmaceuticals would boost access to nuclear medicine in EU periphery Member States.

What are the main opportunities and challenges for the digital transformation and AI in medical applications using radiation sources?

In imaging applications, AI and high-performance computing are expected to improve workflow and productivity by improving the imaging chain from patient scheduling to data acquisition, image processing, image quality optimization and interpretation. Additionally, AI technology may enhance clinical and research capabilities through innovative drug design, and identification of imaging biomarkers. While in therapeutic applications, AI methods are expected to accelerate drug design, support radiobiology research, and personalize radiopharmaceutical therapies, with consequent better patient outcomes. Challenges are present at different levels that comprise legal, ethical, structural, and especially educational issues. Consequently, a framework that includes legal, industry, health, and citizens' perspectives, is needed to advance the health sector.

What role could AI play to attract the younger generation to careers in the area of medical applications of ionising radiation?

The main challenges in AI development may be grouped in general issues (shared with fields other than healthcare) related to data, AI tools reliability, digital infrastructure, and regulation, which are getting attention and funding from several European Calls. Further challenges are shared within health-related fields. These include among others regulation on responsibility and liability, ethical development, clinical implementation strategy and health professionals' involvement in terms of responsibility and development (the "in-the-loop" vision). Different educational strategies according to career stage should be made available. As for challenges in medical applications using radiation sources that should be addressed in future investment programs, these include AI-enhanced drug discovery supported by the wider availability of radionuclides; AI-derived biomarkers research and validation; radiobiology research supported by high-performance computing, AI methods, and cutting-edge technological equipment. To attract the younger generation, innovative training programs and doctoral courses proposed early during the educational path need to be developed. Engineering and data science competencies should be provided alongside biological, pharmaceutical, chemical, physics, and medical competencies in the ionizing radiation field. Innovative roles and careers should be promoted by successful models in advertising and communication campaigns.

RECOMMENDATIONS AND NEXT STEPS

Mariya Gabriel, European Commissioner for Innovation, Research, Culture, Education and Youth

The Roundtable discussion is a useful platform to help move forward research and innovation with concrete initiatives, aligning relevant stakeholders, the Member States and the industry. The following are key takeaway messages that were highlighted from the exchanges with stakeholders.

First is the need to boost synergies with Euratom and other EU programmes, among DGs, stakeholders and with Member States in the areas of energy transition and health considering the important role that digital technologies and AI can play in both areas discussed:

- **On SMRs:** To build a stronger EU industry chain and promote synergies in Europe and, later on, with international trusted partners (US). The initiative should address issues in the nuclear field like cyber security, digital twins, and environmental characterisation. Existing synergies of Euratom Research with DG ENER and JRC should continue to be capitalised and further synergies with Member States and Horizon Europe Clusters should be developed, e.g. in robotics, materials and energy-intensive industries.
- **On medical applications:** As medical radioisotopes broaden from diagnosis to therapy, with the so-called 'theranostics', their reliable supply, as well as quality and safety of medical applications are essential. It is key that further the links are developed with Europe's Beating Cancer Plan, the Mission on Cancer and the SAMIRA Action Plan also thanks to the European Partnership PIANOFORTE on radiation protection.
- **On advanced skills and training:** The Euratom Programme will support with a total of EUR 15 M, two European initiatives on nuclear education and training. The first, OFFERR, will establish an operational scheme facilitating access for researchers to key nuclear science infrastructures. The second, ENENplus, is the largest and most integrative nuclear Education and Training effort up to date, that supports cross-border and cross-disciplinary mobility within and beyond the EU in cooperation with JRC, OECD/NEA and international partners including the US, Korea and Japan.

Current Euratom Research Initiatives

A number of current Euratom initiatives can be leveraged to boost synergies with other EU programmes in the areas of energy transition and health. Three relevant initiatives under the Euratom Programme call for proposals 2021-2022 (EUR 100 M) will contribute to:

- The safety of SMRs (Light Water with passive mitigation strategies) and the exploration of Generation IV reactor possibilities (3 projects with EUR 15 M of Euratom contribution).
- The safe use and the reliable supply of radionuclides for diagnosis and therapy, and a European Partnership on Radiation protection and medical applications (EUR 30 M).

- A pan-European Nuclear Competence Area for a revamped Education and Training in nuclear science and technology (EUR 7 M).

Next Nuclear Roundtable

Taking stock of the advancement of the preparation of these initiatives, the next Nuclear Roundtable could focus on:

- Opening access to nuclear research infrastructures in Europe.
- Monitoring cancer diagnosis and treatment inequalities.

ANNEX – CURRENT ACTIONS ON SMRS AND MEDICAL APPLICATIONS

EURATOM RESEARCH AND TRAINING PROGRAMME 2021-2025

AMR: ECC-SMART - Joint European - Canadian- Chinese Development of Small Modular Super - Critical Water-cooled Reactor Technology

Duration 48 months, September 2020 to August 2024, EC contribution EUR 4 M, coordinated by Centrum Vyzkumu Rez Sro (Czechia).

- Important international cooperation aspect with the participation of CNL from Canada and of entities from China (NPIC, a subsidiary to China National Nuclear Corporation-CNNC).
- Feasibility and identification of safety features of an intrinsically / passively safe SMR cooled by supercritical water (SCWR-SMR).
- Collect the experience gained on the development of SCWR in Europe, Canada and China to derive a joint design requirement document - basis for a future conceptual design project of a SCW-SMR.
- Experimental and numerical work: behavior of materials, validation of the codes and design of the reactor core.

LW SMRs: McSafer - High-Performance Advanced Methods and Experimental Investigations for the Safety Evaluation of Generic Small Modular Reactors

Duration 36 months, September 2020 to August 2023, EC contribution EUR 4 M, coordinated by Karlsruher Institut Fuer Technologie (Germany).

- Safety aspects for LW-SMRs.
- Dedicated experimental investigations and numerical simulation.
- Data for code validation.
- Advanced computational tools developed and partly validated in the European projects NURESAFE, HPMC and McSAFE, to conduct the neutron physical, thermal hydraulic and thermo-mechanic analysis of the reactor core of different SMR designs.
- The methodology is fully transferable to LWR as well as to Gen-IV reactors.
- CNEA from Argentina participates in this project.

LW SMRs: ELSMOR - Towards European Licencing of Small MOdular Reactors

Duration 42 months, September 2019 to 28 February 2023, EC contribution EUR 3.5 M, coordinated by Teknologian Tutkimuskeskus VTT Oy (Finland).

- Dialogue with the public, decision makers and regulators.
- Methods and tools to assess and verify the safety of LW-SMR.
- Experimental campaigns and numerical simulation.
- Improvement of the European nuclear safety analysis codes and the experimental research infrastructures.

AMR: GEMINI+

Duration 42 months, September 2017 to 28 February 2021, EC contribution EUR 4 M, coordinated by Narodowe Centrum Badan Jadrowych (Poland).

- GEMINI+ will provide a conceptual design for a high temperature nuclear cogeneration system (HTGR) for supply of process steam to energy intensive industry, a framework for the licensing of such system and a business plan for a full-scale demonstration.
- GEMINI+ was conceived as a joint effort between the NGNP Industry Alliance (USA) and the NC2I (Europe) to promote the industrial development of HTGR cogeneration. Participation of the JAEA from Japan, KAERI from Korea reinforced the international cooperation (INCO) aspect.

EURATOM PROGRAMME - DIRECT ACTIONS CONTRIBUTING TO THE SUPPLY OF MEDICAL RADIOISOTOPES

Sustainable and Resilient Supply of Medical Radioisotopes (SMER reports)

JRC completed two studies on the EU market of medical radioisotopes (Sustainable and Resilient Supply of Medical Radioisotopes, SMER) which include the following recommendations:

- Improving official annual data collection on the use of radiopharmaceuticals.
- Supporting research, innovation and training in novel radionuclide therapies and pharmaceuticals.
- Fostering an active role at European level.
- Enhancing information-sharing regarding supply capacities, new builds, demand expectations and outages for key therapeutic radionuclides.
- Exploring the possibilities for and desirability of EU-level negotiations on price and contractual conditions.

Project RadioMed (Radionuclides for Medicine)

The work programme includes: 1) the development of economically sustainable methods for the artificial production of the relevant radionuclides; 2) a study of the stability of supply and emerging challenges in the market of medical radioisotopes in the EU. This project is supporting the 1st pillar of the SAMIRA Action plan on securing the supply of medical radioisotopes.

Exploratory Research Programme, Ir-NANO

The project is meant to develop alternative production routes from accelerators of Mo-99 radionuclides for medical applications based on the irradiation of colloidal suspensions of metallic nanoparticles. The process may facilitate the preparation of medical radionuclides.

JRC infrastructures contributing to the investigation of alternative routes for radioisotope production

The GELINA and MONNET facilities offer support to production studies for medical radionuclides through the JRC Open Access program EUFRAT. The PAMEC facility supports a variety of applications, including medical applications, and the FMR facility focusing on fuel preparation and characterization, as part of its association with the PAMEC facility.

Targeted Alpha Therapy

The projects supports: (1) the development and clinical testing of radionuclides for targeted alpha therapy of cancer; (2) the standardisation of protocols for clinical application of targeted alpha therapy; (3) training and knowledge transfer on alpha therapy alpha emitters for cancer therapy of staff (physicians, physicists, radiochemists). These activities contribute to the 2nd pillar of the SAMIRA Action plan on quality and safety and to the 3rd pillar on innovation and technological development.

Work on standardisation related to Radionuclide calibrators in hospitals

Action 8 in the 2020 Annual Union Work programme for European Standardisation with the aim to combine existing international standards into a single standard and create a joint working group to combine 4 ISO and IEC (International Electro-technical Commission) standards into a single one to achieve more clarity and trust.

Support to the European Observatory on the Supply of Medical Radioisotopes

The European Observatory (established by the Commission in 2012) brings together all relevant information to the EU decision makers to support strategies and policies for their implementation. It is composed of members from the Euratom Supply Agency, the European Commission (DG ENER, JRC, R&I, SANTE and GROW), the European Association of Nuclear Medicine (EANM) and various industry stakeholders (NMEu). Its four strategic objectives are 1) support a secure Mo-99/Tc-99m supply across the EU; 2) ensure that the Mo-99/Tc-99m supply issue is given high political visibility; 3) encourage the creation of a sustainable economic structure of the supply chain; 4) establish periodic reviews of the supply chain and capacities.

SAMIRA ACTION PLAN – FOCUS ON EU R&I SUPPORT

This action will aim to develop and implement a research roadmap for non-power applications of nuclear and radiation technology. The main objective is to develop a strategic plan and identify common actions between the 'Health' cluster of the Horizon Europe and the Euratom Research and Training Programme in the 2021 2025 period. In particular, pharmacological and clinical research into novel radioisotope therapies and diagnostic tests will complement actions proposed in section 2 with regard to the production of radioisotopes. This action should further facilitate the access of European researchers and industry to top-class accelerator research and test infrastructures.

Main deliverables and timelines

Action		Deliverables	Indicative time-table	Funding and lead DG
EU research and innovation support		Research roadmap for medical applications of ionising radiation technologies	2023	Horizon Europe DG R&I (Euratom)
		Roadmap implementation through specific actions funded under HE Health and Euratom Work Programmes	2024	Horizon Europe DG R&I (Euratom + Health)
		Results from research on the health effects of medical ionising radiation	2022-2026	Euratom programme DG R&I

Research roadmap for medical applications of ionising radiation technologies

The Euratom funded project[39] aims to develop a roadmap for coordinated European research and innovation in medical applications of ionising radiation, based on extensive stakeholder consultation and building on existing and planned research activities in the field. The roadmap will provide an integrated framework for future calls for proposals in this area, leading to synergies between the Horizon Europe Health cluster and the Euratom Programme. Roadmap will benefit from inputs and the active involvement of European stakeholders from the clinical, industrial, regulatory, and scientific fields. This action will provide guidance to

[39] EURAMED rocc-n-roll project https://cordis.europa.eu/project/id/899995.

stakeholders and the Commission on the steps needed in the coming years for the development of research activities and knowledge in this area.

Research roadmap implementation

The roadmap's recommendations will be considered by the Commission services for inclusion, after 2023, in the Euratom and Horizon Europe work programmes. The corresponding calls for proposals will support research and innovation into medical applications of ionising radiation in priority areas identified by the work programmes. The implementation of the roadmap should follow the proposals made in previous sections of this Action Plan.

Research on the health effects of medical ionising radiation

The activities foreseen under this section will benefit from research in the health effects of ionising radiation, as foreseen under the Euratom Programme 2021-2025. Euratom will continue supporting fundamental research in this area[40] and further focus efforts on research into the health effects of the medical applications of ionising radiation, taking into account existing research agendas.[41]

[40] Based on the roadmap prepared by the CONCERT, project https://www.concert-h2020.eu/.
[41] Developed by the EURAMED and the EURADOS platforms.

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This High Level Nuclear Roundtable discussed two key areas that require Research and Innovation action: Small Modular Reactors and Medical applications using nuclear technologies. For both areas, Artificial Intelligence is identified as a common denominator that could drive innovation and cross-fertilisation between fields.

Research and Innovation policy

Publications Office
of the European Union