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SAMIRA Study on the implementation of the Euratom and the EU legal bases with respect to the therapeutic uses of radiopharmaceuticals

Project Workshop
11–12 December 2023

This project has received funding from the European Commission under Service Contract N°ENER/2022/NUCL/SI2.869532.

Welcome and opening

Georgi Simeonov – DG ENER-D4 Radiation Protection
Michael Lassmann – SIMPLERAD consortium

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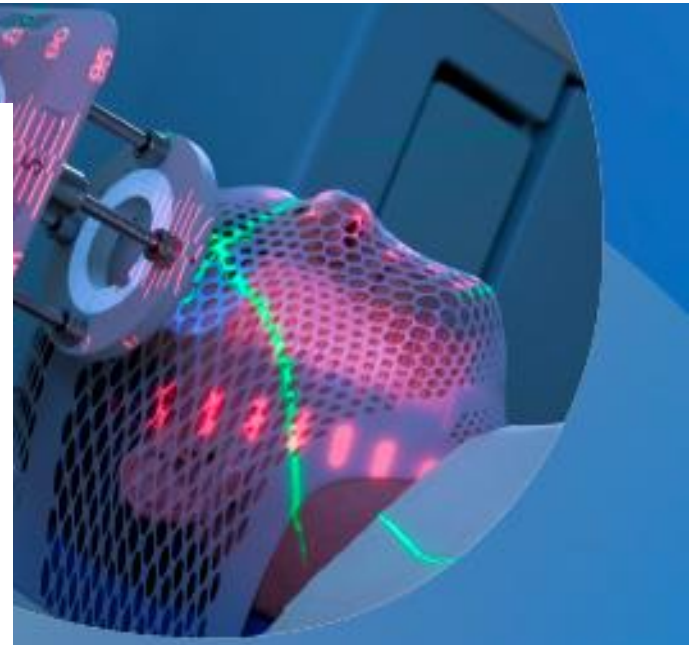
*"This action plan will ensure that the EU continues to be the **global leader** in supplying **medical radioisotopes** and developing **radiological diagnostics and treatments,** while applying the **highest quality and safety standards**."*

*"The **SAMIRA Action Plan is our first deliverable under Europe's Beating Cancer Plan**, and it is an excellent example of collaboration between the energy, health and research communities."*



Security of supply of medical radioisotopes

- Launch of the European Radioisotope Valley Initiative (ERVI)
- Secure supply of source materials for production of radioisotopes
- Support to long-term sustainability of radioisotope production in Europe

Quality and safety of medical ionising radiation applications

- Launch of the European Initiative on Quality and Safety of medical applications
- Improvements to workforce availability, education and training
- Support for equal access to modern technology and interventions

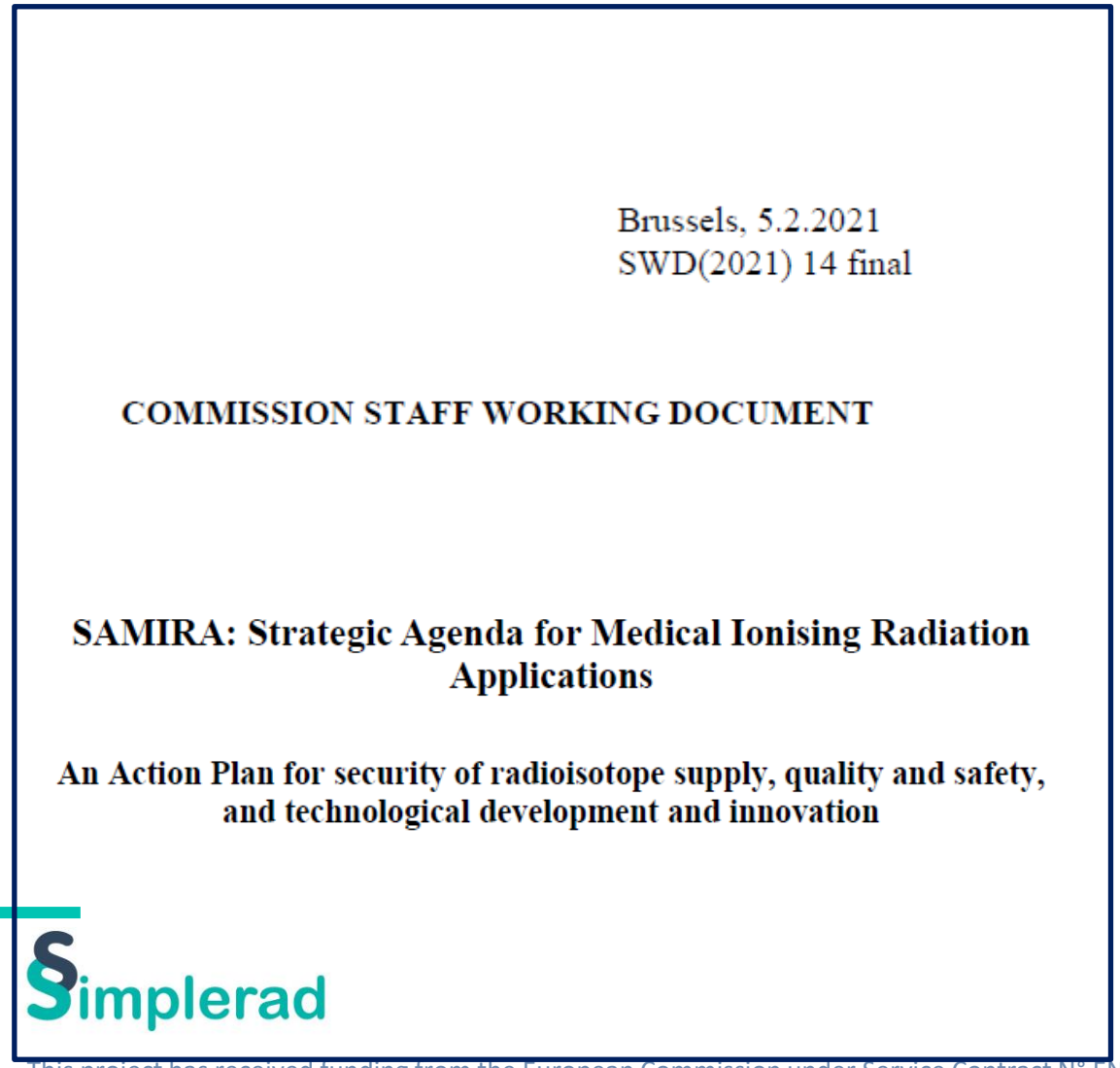
Innovation and technological development

- Research roadmap for medical applications on ionising radiation technology
- Joint Health Technology Assessment of technologies and interventions involving ionising radiation

#EUSamira
#EUCancerPlan

European Commission

Therapeutic nuclear medicine in the SAMIRA Action Plan



Brussels, 5.2.2021
SWD(2021) 14 final

COMMISSION STAFF WORKING DOCUMENT

SAMIRA: Strategic Agenda for Medical Ionising Radiation Applications

An Action Plan for security of radioisotope supply, quality and safety, and technological development and innovation

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- Forecasted ***considerable growth of*** the market for ***novel therapeutic radiopharmaceuticals*** by 2030
- Radiopharmaceuticals are regulated under the EU pharmaceutical and radiation protection regimes, with important ***implications for clinical trials, drug authorisations*** and routine clinical use
- There is a scope to ***improve coordination*** in implementing the ***different regulatory frameworks***

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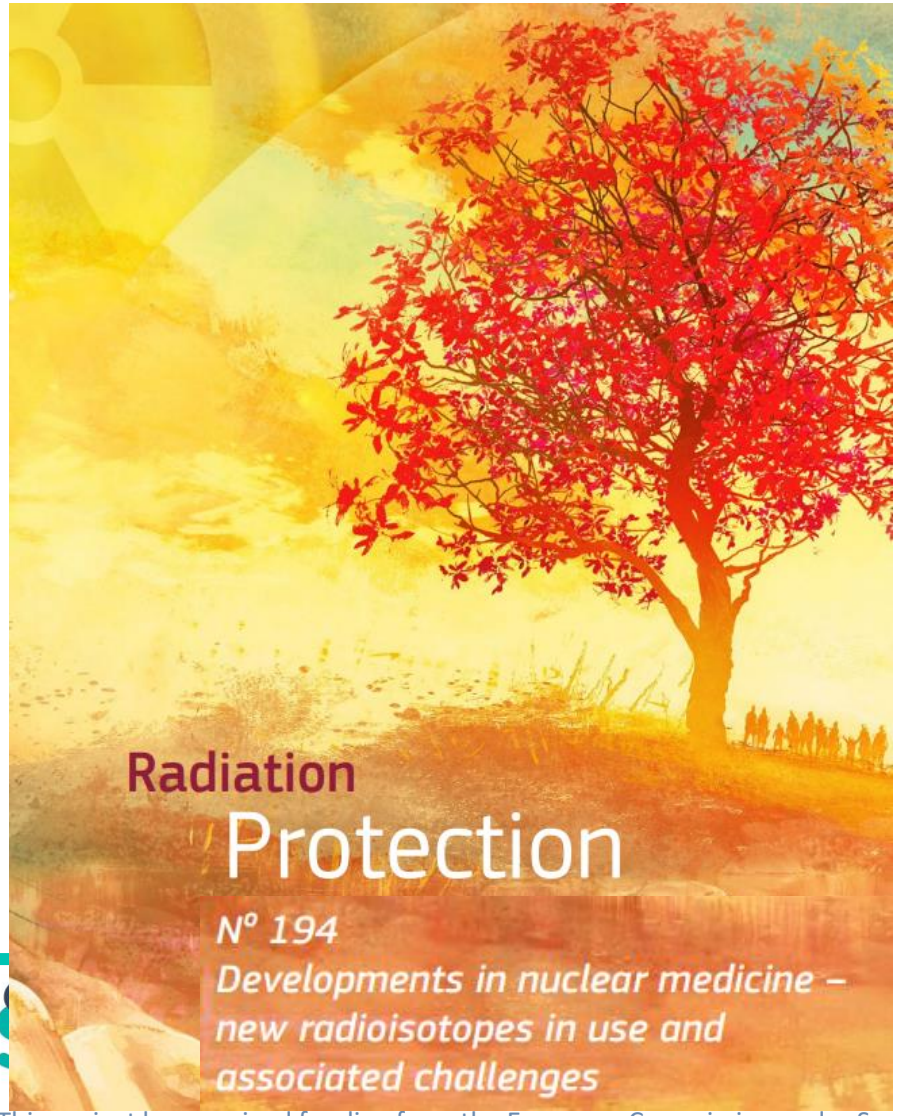
2019 Euratom Scientific Seminar



- Needs to increase the ***implementation of individual dose planning and post-treatment verification*** as well as the systematic involvement of medical physicists
- Requirements for obtaining ***marketing authorization*** for new radiopharmaceuticals should be strengthened to ***entail sufficient dosimetry data*** from early clinical trials
- ***Personalized treatment planning*** methods should be ***part of the market registration process*** for radionuclide therapies, enabling their placement within the realm of radiotherapies instead of chemotherapy

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Welcome and opening

Michael Lassmann – SIMPLERAD consortium

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Workshop house rules

- Online audience may submit questions and comments to the speakers via the Q&A function
- Moderators will officiate discussion at the end of each session, recognising onsite audience and reading questions from the online audience
- Microphones are provided in the aisles so audience members can ask questions
- Speakers will try to answer all questions/comments during the webinar or will answer in writing afterwards

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Day 1 programme

13:00–14:15	**Session 1: Opening & Setting the Scene**
	Welcome, introduction, European framework, perspectives of international organisations, discussion (15 minutes)
14:15–15:15	**Session 2: Interrelations among Legal and Regulatory Frameworks [WP1]**
	WP1 analysis, comparative legal analysis, legal basis in the UK, discussion (10 minutes)
15:15–15:45	**Coffee break**
15:45–17:45	**Session 3: Survey and Expert Interviews on European Legal Requirements [WP2]**
	Survey and interview results, member-state field reports, discussion (30 minutes)
17:45–18:00	Wrap-up and conclusions

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Registration

144 total registrations
98 onsite / 38 online

PR = consortium
AB = Advisory Board
ES = Euro. professional society
NS = nat'l professional society
IN = industry
HP = health professional
CA = competent authority
EC = European Commission
OT = other

Austria	5	4 PR, 1 OT		**Latvia**	2	2 CA
Belgium	22	2 PR, 5 AB, 1 ES, 2 NS, 1 IN, 3 HP, 4 CA, 2 EC, 2 OT		**Luxembourg**	5	3 EC, 2 CA
Bulgaria	1	1 EC		**Malta**	1	1 NS
Croatia	1	1 WPMED		**Netherlands**	9	2 PR, 2 HP, 1 NS, 2 EC, 1 OT, 1 SGQS
Czechia	4	2 CA, 2 PS		**Norway**	3	1 PR, 2 CA
Denmark	2	2 CA		**Poland**	1	1 PS
Estonia	2	2 CA		**Portugal**	2	1 SGQS, 1 WPMED
Finland	4	1 CA, 3 NS		**Romania**	1	1 ES
France	10	1 PR, 2 CA, 3 NS, 1 EC, 3 OT		**Slovakia**	1	1 NS
Germany	22	5 PR, 1 AB, 1 EC, 4 IN, 4 HP, 1 CA, 3 NS, 3 OT		**Spain**	3	1 HP, 2 CA
Hungary	2	1 CA, 1 NS		**Sweden**	7	2 AB, 1 ES, 1 NS, 1 HP, 2 CA
Ireland	4	1 ES, 2 CA, 1 WPMED		**Switzerland**	5	2 IN, 1 CA, 2 NS
Italy	4	1 EC, 2 HP, 1 CA		**Non-EU**	11	UK 9, Colombia, Ukraine
				No rep		Cyprus, Greece, Lithuania, Slovenia

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