EN



Brussels, 12 June 2024 (OR. en)

11115/24

RECH 308 ATO 45 INTER-REP 60

COVER NOTE

Subject:	The European research roadmap for medical applications of ionising radiation
	 Powerpoint presentation (Research (Atomic Questions) WP meeting 12.06.2024)

This document contains a presentation by an external stakeholder and the views expressed therein are solely those of the third party it originates from. This document cannot be regarded as stating an official position of the Council. It does not reflect the views of the Council or of its members.

11115/24 ALDSR/lv COMPET.2.





The European research roadmap for medical applications of ionising radiation

Christoph Hoeschen
On behalf of the EURAMED rocc-n-roll project consortium

Working Party on Research (Atomic Questions) 12th of June





Disclosures

- Christoph Hoeschen was the Scientific coordinator of the EURAMED rocc-n-roll project.
- This project has received funding from the Euratom research and training programme 2019-2020 under grant agreement No 899995.







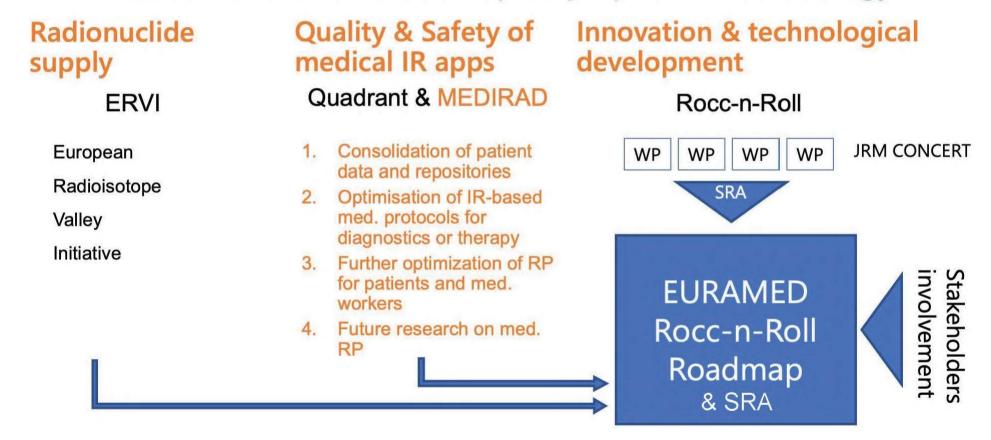
Perspective of the Research Roadmap for Medical Applications of Ionising Radiation

- Roadmap developed from the perspective of Patient's benefit-risk balance
- Identifying the needs in subsequent stages of life
- Challenges identified in developed SRA on ionising radiation and related radiation protection are the basis of the Roadmap
- Fits well into SAMIRA agenda
- And makes use of and complements other initiatives
 (EUROFUSION, EURAD, PIANOFORTE, ENEN, EUCAIM)



SAMIRA Strategic Agenda for Medical IR applications:

Situation of the RnR roadmap as proposed methodology





Project Data

• Name: EURopeAn MEDical application and Radiation prOteCtion Concept: strategic research agenda aNd ROadmap interLinking to heaLth and digitisation aspects

Acronym: EURAMED rocc-n-roll

• Call/Topic: Research roadmap for medical applications of ionising radiation

• Type of action: Coordination and support action

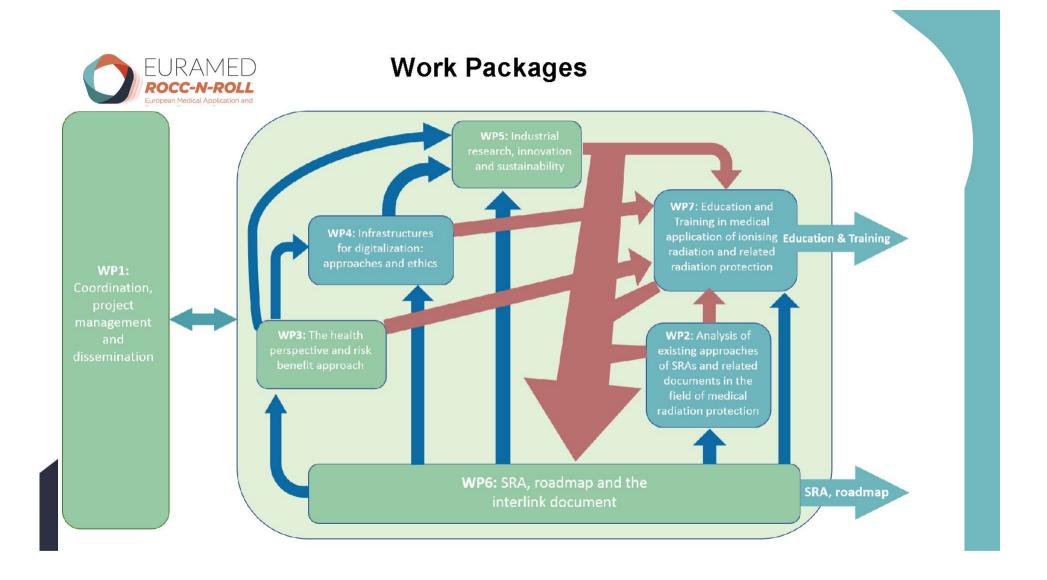
Duration: 36 months

• Start date: September 1, 2020

• End date: August 31, 2023

• **Grant Amount:** 1,959,175.00



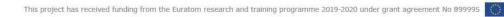




Working principle

- 29 partners
- Have set up tasks and task members
- Advisory board for support (from many of the EU countries not represented as partners)
- Additional external experts named based on workshop and panel concept





Outputs

Strategic research agenda (SRA)

Defining the needs, gaps and opportunities for research in medical application of ionizing radiation and radiation protection.

* based on the existing EURAMED SRA

Roadmap

Highlighing game changers;

Transferability into sustainable production and clinical practice;

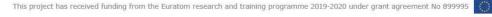
Predicting timelines and budgets;

Ultimately improving patient care.

Interlink document

Showing the potential interactions and relations between the different components of the SRA;

Representing the interlinks to nearby fields.





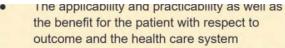
SRA



Chapter 1 Chapter 2 **Medical Applications of Ionising** Quality and Safety Measures Including initiate **Radiation Protection** Radiation Precision imaging for individualised health Decision support systems and Al based motivate methods to reduce the radiation burden for (New) molecular imaging methods for patients and staff and measure exposure understanding localised molecular aspects and quality parameters of diseases Technological improvements allowing better Artificial Intelligence / use of healthcare data benefit-risk balances for improved diagnosis and therapy Reliable exposure determination including Image quality and higher accuracy for its spatial distribution image-based diagnostics Full elaboration of such exposure New therapeutic tools determination for newly emerging Optimisation and broad and quality-assured technologies implementation of existing diagnostic Evaluation of image quality in imaging imaging and therapeutic applications procedures and dose volume histograms in including interventional procedures therapeutic applications Combination with other therapies - synergies Taking into account patients' benefit of the and detrimental aspects medical application of IR, potential risks Theranostics have to be addressed based on radiation Improved medical care for paediatric biology knowledge patients and pregnant women Understanding of individual sensitivity and Screening susceptibility and the influencing factors Ethical aspects and implementation of the including effects of the diseases patient's perspective Ethical considerations regarding the use of Applications as well as the data used for IR in medicine and the corresponding support generation or evaluation of tools must be benefit-risk balance quality assured Efficient monitoring of staff exposure using The applicability and practicability as well as new technological approaches and for all ensure the benefit for the patient with respect to applied procedures outcome and the health care system Evaluations of improved or new techniques need to be done evidence-based support define define Chapter 3







 Evaluations of improved or new techniques need to be done evidence-based ensure

new technological approaches and for all applied procedures

define

support

define

Chapter 3 Organisational Requirements

- Fit-for-purpose support structures for the research and innovation system
- Technology transfer
- All relevant digitalisation aspects
- Education and Training (E&T) for existing and future medical staff

Specifically:

- Potential Centres of Excellence (CoEs) on medical applications of IR and medical RP research
- Sustainability of resources for new and existing applications
- Ensuring clinical implementation of innovation including corresponding financial aspects across countries in Europe
- Digitalisation in the field of medical applications of IR for personalised medicine and electronic health records, RP, standardisation of data formats and Artificial intelligence (AI)
- Digitalisation in the field of medical applications of IR is related to a number of ethical issues and accompanying research needs like diversity, inclusion, and equity concerns related to personalised medicine
- Effective clinical decision making in the context of (potentially) biased datasets
- Implementing and updating the education and training in medical applications of IR and related quality and safety aspects
- Transfer and translation in the field of medical applications of IR is an ongoing challenge for a useful innovation chain







European Research Roadmap For Medical Applications of Ionising Radiation for Better and Individualised Healthcare to Improve Patients' Lives

Vision

- improve patient care in Europe especially for cancer patients, patients suffering from cardiovascular diseases and neurovascular diseases.
- **provide guidance** to European policymakers, funders, and the scientific and clinical communities regarding research priorities, infrastructure development, and education and training actions.
- proposed actions are prioritised regarding their impact on patients' life expectancy and/or quality of life,
- radiation protection should be recognised as an integral part of quality and safety measures.
- to drive **progress in personalised medicine** using medical applications of IR in Europe.
- this requires crucially the strong implementation of clinics into the research activities.





Roadmap organised using concept of breakthroughs

The roadmap defines breakthroughs as

"Research and technological developments that may substantially impact medical applications of ionising radiation from the perspective of patients' life expectancy and/or life quality, radiation protection and health care systems".



Generic breakthroughs





Patient-related R&D Breakthroughs 1 - 4

1. Improve / develop diagnosis

- > Decision-making
- > Technical developments including AI-based methods
- Screening
- Molecular imaging methods
- Quantitative imaging and radiomics

2. Improve / develop therapy

- Radiation oncology
- > Theranostics
- > Interventional procedures

3. Patient radiation protection and benefit-risk ratio

- Radiation biology
- > Patient dosimetry

4. Patient relations

- ➤ Individual benefit-risk balance assessment
- > Involvement of patients in research
- Shifting the communication landscape
- > Ethical data management



0

Generic Breakthroughs 5 - 8

5. Strategic positioning of applications of IR in medicine

- Comparison of benefit-risk with other medicine
- > Synergies with non-IR techniques
- Economical aspects and funding of R&D

6. Implementation, sustainability, and organisation of IR-based medicine

- > Translation & organisation
- Research for sustainable supply including radionuclides
- Access to data, biobanks and equipment
- > Harmonisation of data and protocols

7. Quality, safety, and legislation in Europe

- Quality determination
- Q&S for diagnosis and therapy
- Clinical quality and safety audits
- Improve the safety culture
- > Harmonisation of EU legislation

8. Career attractivity and radiation protection for workers

- Career attractiveness
- Radiation protection for workers





Patient related breakthroughs require highest budget

Implementation of improved diagnosis or therapy requires

A: Basic research on clinical questions and biology (0.5 to 10 million euro)

B: Basic research on new technological approaches (1 to 50 million euro might apply, e.g., to new hadrontherapy sources)

C: Research on possibilities for patient-centred implementation (1 to 5 million euro)

D: Research on ethical implications (0.5 to 3 million euro)

E: Technological transfer (0.5 to 20 million euro)

F: Clinical studies to prove evidence for the advantages of the proposed new or optimised methods (2 to 10 million euro)

Smaller amounts needed for other BTs





Impact of breakthroughs

IMPACT criteria:

- number of European patients potentially benefitting from the innovation
- improvement of life quality of patients, including patient comfort and patient safety, including RP
- increased life expectancy
- improved healthcare from a societal perspective, including financial and organisational improvements

A reasonable progression of all BTs in a balanced way is desirable





Impact of breakthroughs - example:

IMPACT example: Decision making in diagnostic procedures

- number of European patients potentially benefiting from the innovation very high
- improvement of life quality of patients, including patient comfort and patient safety, including RP high
- increased life expectancy high
- improved healthcare from a societal perspective, including financial and organisational improvements – very high





Conclusions I

- European patients especially those suffering from cancer, cardiovascular, neurovascular, infectious and inflammatory diseases as well as other diseases including rare diseases can benefit very strongly from new or optimised medical applications of ionising radiation.
- There are new technologies like artificial intelligence, new radiation sources, nanomaterials, new detector concepts and new insights into biological questions that can allow great advances in European patient care.
- Application of IR in medicine can by nature be and foster personalised medicine, actually it is in many cases the cheapest and easiest approach to personalized medicine.
- Medical application of IR will allow improved healthcare also from a societal perspective, including financial and organisational improvements.



Conclusions II

- The great chance inherent in the best use of medical applications of IR in Europe needs sufficient research efforts and corresponding funding.
- It is absolutely mandatory to have the clinical research institutions with close links to clinics and patient care drive the research and be strongly involved in it. This includes all fields of medical applications of IR: radiology, interventional radiology, radiation therapy and nuclear medicine, all of them always supported by medical physics, radiographers/technicians and biologists etc.
- Quality and safety including radiation protection is a central necessary component of meaningful and benefical use of IR in medicine. The EURATOM program is already supporting the related research as well as corresponding education and training and need to go on with that support as well as support for radiation biology and waste management research.
- To tap the full potential of the new or optimized applications of IR in medicine a common approach between Horizon Europe, especially cluster 1 potentially with a focus at the moment on the mission on cancer, but not limited to that mission, and also other clusters.





! THANK YOU FOR YOUR ATTENTION!

https://op.europa.eu/en/publication-detail/-/publication/dc4597d8-ea77-11ee-bf53-01aa75ed71a1





ANNEXE





IMPACT criteria:

- number of European patients potentially benefiting from the innovation
- improvement of life quality of patients, including patient comfort and patient safety, including RP
- increased life expectancy
- improved healthcare from a societal perspective, including financial and organisational improvements

A reasonable progression of all BTs in a balanced way is desirable



	Increased life expectancy	Improvement of life quality (comfort and radiation protection)	number or patients benefiting from innovation
--	---------------------------	--	--

PATIENT-RELATED BREAKTHROUGHS				
BT 1 IMPROVE/DEVELOP DIAGNOSIS	very high	high	high	high
Decision-making	very high	high	high	very high
Technical developments including Al-based methods	very high	high	unclear	high
O Screening	very high	undear	high	very high
Molecular imaging methods	high	very high	high	high
Quantitative imaging and radiomics	high	very high	high	high
BT 2 IMPROVE/DEVELOP THERAPY	high	very high	very high	high
Radiation oncology	high	very high	high	high
O Theranostics	medium	high	high	high
O Interventional procedures	high	very high	very high	very high
BT 3 PATIENT RADIATION PROTECTION AND BENEFIT-RISK RATIO	very high	high	rnedium	medium
Radiation biclogy	very high	high	medium	medium
O Patient dosimetry	very high	medium-high	medium-lcw	medium
BT 4 PATIENT RELATIONS	very high	high	medium-lcw	medium
O Individual benefit-risk balance assessment	very high	very high	medium-low	medium
Involvement of patients in research	medium-low		medium	high
Shifting the communication landscape	very high	high	medium low	
Ethical data management	very high	high	unclear	high

GENERIC BREAKTHROUGHS				
BT 5 STRATEGIC POSITIONING	medium-high	potentially high	potentially high	very high
O Comparison of benefit-risk with other medicine	high	high	high	very high
Synergies with non-IR techniques		potentially high	potentially high	high
Economical aspects and funding of R&D	medium	high	high	very high
BT 6 IMPLEMENTATION AND SUSTAINABILITY	high	high	high	high
O Translation & organisation	high	high	high	high
Research for sustainable supply including radionuclides			medium-high	
Access to data, biobanks and equipment	medium	medium-high		high
Harmonisation of data and protocols	very high	medium-high	high	high
BT 7 QUALITY, SAFETY AND LEGISLATION IN EUROPE	high	high	medium-high	high
Quality determination	high	high	medium-lcw	high
O Q&S for diagnosis and therapy	high	high	medium-high	high
Clinical quality and safety audits	high	high	high	medium-high
Improve the safety culture	medium-high	high	medium-low	
O Harmonisation of EU legislation	high	high	medium-high	
BT 8 CAREER ATTRACTIVITY AND RADIATION PROTECTION FOR WORKERS	high	medium-high	medium	high
Career attractiveness	high	medium-high	medium	high
Radiation protection for workers	medium-low		medium-low	medium-high

Table 1: Suggested evaluation of BTs potential impact. The impact of research projects to be funded will have to be evaluated in more detail. The different impact-related indicators may serve as guides for funding research proposals, amongst other indicators. Eventually, a balanced scoring on the different impact indicators is suggested to evaluate a full research work programme, including all research projects. The category looking for the number of patients / citizens benefitting from improvements is defined really along the lines on how many persons will really see a change (not are affected at all).





