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D3.5 Common interests in RP and synergies between Health Cluster in Horizon Europe and the Euratom Programme

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Abbreviations

AI	Artificial Intelligence
COCIR	Comité Européen de Coordination des Industries Radiologiques Electromedicales et d'Informatique de Santé Aisbl
EC	European Comission
ECO	European Cancer Organisation
EHDS	European Health Data Space
EMC	Erasmus Medical Canter
EOSC	European Open Space Cloud
ERPW	European Radiation Protection Week
ESR	European Society of Radiology
EUC	European University of Cyprus
FAIR	Findable, Accessible, Interoperable, and Reusable
FFGM	Fondazione Toscana Gabriele Monasterio
IGG	Istituto Giannina Gaslini
LNT	Linear No Threshold Model
OvGU	Otto-Von-Guericke-Universität Magdeburg
RP	Radiation Protection
SRA	Strategic Research Agenda
TEHDAS	Towards European Health Data Space
TG	Task Group
UGENT	Universiteit Gent
UmU	Umea University
UP	Université Paris Descartes
VHIO	Fundacio Privada Institut d'investigacio oncologica de Vall-Hebron

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1. Introduction

In WP3, the tasks 3.1-3.4 deliver input on medical application of ionizing radiation in oncology, neurovascular, cardiovascular and in other relevant clinical scenarios, with focus on pediatric patients, pregnant women, chronic diseases, and screening programmes. Task 3.6 delivers input on the needs and opportunities regarding the patient perspective on radiation-based health care and radiation protection (RP) research. Task 3.5 identifies the common radiation application and RP research interests and needs of Tasks 3.1-3.4 and 3.6 and address the aspects related to individual health assessment as input to WP6. Following an analysis of the Horizon Europe Framework Programme for Research and Innovation with a view to identify synergies with the Euratom Research and Training Programme 2021-2025, Task 3.5 also identifies the main interlinks between health-related research and RP-related research and how these two areas could cross-fertilise each other and be more synergistic in the future. Also, pathways how new developments in the clinical field of relevance to RP will be proposed. Task 3.5 will provide input to Task 6.3 as regards suggestions to the EC on how to decide in which funding schemes to integrate future RP research aspects to create synergies and to avoid duplication.

2. Methodology

The work in TG 3.5 is a collaboration between the task leaders of the TGs in WP 3 together with other partners in the consortium. The task is led by UmU and OvGU, UP, VHIO, FTGM, IBG, ECCO, COCIR, EUC, EMC, EURAMED are partners.

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Table 1. Composition of TG 3.5

The activities

The members in TG 3.5 are all participating in any of the TG 3.1-3.4 or 3.6. No panel was selected for task 3.5. A common questionnaire for all TGs in WP 3 was the first activity to identify disease areas for all TGs in WP3. From the result of the questionnaire the first diseases were selected, and at the WP2 workshop in November 2020 the common interests for WP3 were discussed. The material from that workshop has been brought forward to the following WP3 workshop in 2021. From the two workshops in June and November 2021, common

radiation application and RP research interests have been identified. The TG Members also attended the WP6 at the European Radiation Protection Week (ERPW) in November 2021 to discuss to input to the strategic research agenda (SRA). The identified common areas where more research is needed is presented below.

There is a consensus that the patient perspective is the driving key aspect, and this will influence the outcome of the work and the needs of research. TG 3.6 has worked especially with the patient perspective and common aspects from their work is included in the report from task 3.5.

From the disease-specific TGs, common topics for R&D in applications of ionizing radiation and RP are identified as questions raised by all TGs that are not disease specific and can increase the quality of usage of ionizing radiation in medicine. The perceived increase in quality includes both diagnostic and therapeutic aspects, as well as RP issues and improved conditions for clinical routine and research.

A key finding for all topics is that ethical reflections must be included and, especially in the personalised or precision medicine in imaging and therapy, as well as in the AI domain, new ethical issues arise.

Another critical aspect is to create a usable framework for the legal issues pertaining to secondary usage of clinical and health data in cross-border collaborations across and outside Europe. There are ongoing initiatives such as the Joint action Towards European Health Data Space (TEHDAS <https://tehdas.eu/>), which aims to develop European principles for the secondary use of health data and the creation of a European Health Data Space (EHDS <https://ec.europa.eu/health/ehealth-digital-health-and-ca/european-health-data-space/en>).

During the face-to-face consortium meeting in Freising, Germany on 27-28 June 2022, the content of the report from Task 3.5 was presented and further discussed. Some additional suggestions to the report were made during the discussion.

2. Results

The patient perspective

Tasks 3.1-3.4 have worked with different organ groups or diseases, while Task 3.6 has focused on the patient perspective. The work has made it evident that there are several common interests in the various diagnostic and therapeutic medical fields working with ionizing radiation of more general nature. The first thing, which has also been a baseline for the work, is that the patient perspective is the driving key aspect and all research of the medical usage of ionizing radiation and radiation protection in medicine should bring in that perspective.

The ethical aspects

For all identified topics, where appropriate, ethical aspects should be included in the research. In personalised or precision medicine in imaging and therapy new ethical issues arises. A special area is the increasing application of AI in the medical usage of ionizing radiation and radiation protection.

Radiation protection

RP research in medicine is continuous and aims to optimise the usage of ionizing radiation. Technical development of imaging modalities is paralleled with need of RP research aiming to reduce the dose to patient and personnel further with kept or increased image quality.

For therapeutic use of ionizing radiation, RP research is also continuously needed in parallel with the technical development. In treatment the focus is to increase the dose to the treated region with as low dose as possible to the surrounding normal tissues. The nature and the

quality of the radiation as well as the design on how to administer the radiation in relation to treatment effect are some areas where further research is needed. More knowledge about the measurement or calculation of deposited dose is also required. Research is ongoing for new treatment regimens such as heavy particles, protons, α -particles, FLASH-therapy with ultra-high dose rate, but more knowledge is needed also for those before a safe clinical implementation of new technology and treatment regimens can be realised.

There is no dose limit for patients. Instead, a justification process is done for each examination or treatment. Benefit and risk are weighted for each procedure, and if the clinically identified benefit is greater than the risk each procedure is justified. However, an increase in the number of examinations over a short time is seen for some patients. For other patients with a long disease period, many examinations can be justified over a longer time. The question about cumulative radiation dose and stochastic risk, the issue of repeated examinations has been raised to underline that more knowledge is needed while taking into account the benefits of the patient e.g. for oncological staging or therapy control (1-3). This also raises the question of design of surveillance protocols, most important in non-oncological diseases. More knowledge is needed about the estimation of the benefit-risk balance taking all parameters into account. IAEA published 2021 a joint position statement and a call for action for strengthening radiation protection of patients undergoing recurrent imaging procedures (chrome-extension://efaidnbnmnnibpcajpcglclefindmkaj/https://www.iaea.org/sites/default/files/position_statement_final_endorsed.pdf)

The heterogeneity in how different modalities, procedures, and protocols are used for patients with the same symptoms or diagnoses are large. The EuroSafe Imaging initiative (4) and other “Safe” initiatives aim to optimise the use and increase the homogenization. Clinical decision support system such as ESR i-Guide (<https://www.esriguide.org/>) help to use evidence-based examinations for many referrals. However, the i-Guide does not guarantee that the used protocol is optimised. Furthermore, and more specifically, homogenization of nomenclature in medical procedures using ionizing radiation is something that could further improve both medical applications and RP, as well as the synergies between them. Previous holistic attempts were not successful; there is a need to develop research on a pragmatic approach which would solve most of the problems.

Ethics in RP is needed for instance to develop protocols that strikes the balance between patient perspective and clinical needs. Further consideration of the ethical perspective has been underlined by the WHO to complete the basic principles of RP (justification, optimization, and dose limits) (5).

The linear no threshold model

The linear no threshold model (LNT) is used in radiation protection, but the model is questioned for low and very low doses and the effective dose concept is applied for purposes not supported by the scientific fundament (6, 7). Recent research suggests that more knowledge in radiobiology and epidemiology is needed (8, 9). However, the LNT model is not meant to be used for individual risk assessment but for radiation protection purposes only. This must be clearly communicated to staff and especially to patients.

Homogenization

In both imaging and therapeutic applications of ionizing radiation in medicine, there are many recommendations on the selection of modalities, procedures and acquisition or treatment protocols for different diseases are available from both international and national societies, as well as national legislative efforts. Such recommendations should be based on facts and scientific results for the respective clinical question. The homogenization aimed for could increase the consistency in assessment of patients in Europe. An added challenge to the need for homogenization is that there is a need of individualised risk assessment and dose

calculation, which has dependencies to available modalities, procedures, and acquisition or treatment protocols in addition to individualised radiation sensitivity (10, 11).

The secondary use of clinical and health data

To create a usable framework for the legal issues for secondary usage of clinical and health data in cross-border collaborations across and outside Europe is identified by many bodies and several initiatives and projects are on-going. The Horizon 2020 projects in AI4HI (CHAIMELEON, EUCanImage, INCISIVE, ProCAncer-I and PRIMAGE) are all creating solutions for secondary use in AI in cancer. Other European projects such as X-eHealth are creating solutions for both primary and secondary use. The European Health Data Space Proposal for a regulation - The European Health Data Space was published in May 2022 (https://health.ec.europa.eu/publications/proposal-regulation-european-health-data-space_en) and is a step toward a European platform solution. The European Open Space Cloud (EOSC) is another project aiming to create open platform for data sharing for secondary use of clinical data and will be used in conjunction with EHDS (<https://eosc-portal.eu/>).

All these initiative aims to increase the data availability for research, validation, and quality assurance. Data transfer and data storage, sharing in accordance with FAIR-principles (12) creates possibilities for AI development, research, validation, and implementation but also for quality assurance and clinical research. Besides FAIR, the legal, ethical, and societal impact questions are important, and furthermore these need to be more homogeneously interpreted across Europe to make cross-border collaboration more efficient.

Availability to large sets of high-quality imaging data is a prerequisite for development of AI algorithms and radiomics. Virtual reality and robotics are other areas where more research is needed.

Precision imaging in personalised medicine

The healthcare is moving towards data driven processes for patient care, and the medical research towards data driven life science. With the need of large amounts of data, real world data from the clinical healthcare is needed. More research is needed to learn how medical imaging could be personalised based on individual conditions. Such conditions could be certain genotypes or phenotypes such as receptor expression, or individualised radiation sensitivity. The influence of genotype and phenotype on cancer risk of ionising radiation are other areas with knowledge gaps where more research is needed (10). The knowledge about individual sensitivity is limited and the need of patient-specific dosimetry in radiopharmaceutical therapy is one example where today's methods of deciding the treatment dose probably undertreat patients (11, 13). A better understanding of individual radiobiological effect is needed to take the advantages and to develop radiopharmaceutical treatment (14).

The patient's perspective is always in focus and in personalised imaging this must be considered. The benefit-risk balance is crucial when using ionising radiation and the risk acceptance regarding ionising radiation might change during the health care process and is strongly related to the underlying disease. The patient will probably have a different relation to risk before diagnosis and after cure, independent of diagnosis.

Integrated or combined procedures

Imaging biomarkers, biological features visualised with radiological or nuclear medicine methods or provided by such methods for computer-based evaluation is an evolving field. Radiomics, deep learning and other AI-algorithms are some of the methods used (15-17). More research is needed to understand the full potential in these fields. Integration of imaging biomarkers from structural and molecular imaging with different omics such as genomics or proteomics is another field of research with knowledge gaps. Integrated diagnostics has the

potential ramp up the value of included data, but more knowledge is needed to understand the full potential.

Higher accuracy

The strive for increased image quality in radiology and nuclear medicine will probably never end. The accuracy is presently far from 100% and the possibility for early detection is rather limited. The technology development of scanning equipment is still moving forward and the photon counting CT is one recent example to reach higher image contrast and resolution with decreased radiation dose (18-21). AI algorithm-based reconstructions are other examples on how higher accuracy is aimed (22). Research to prove, validate and show gain for the patients by using these techniques in terms of better diagnosis, improved benefit-risk ratios or cost-effectiveness is needed. In nuclear medicine, research to find even more specialised tracers for PET- and SPECT-studies are on-going. The European initiative PRISMAP - your European provider for medical radionuclides and beyond (www.prismap.eu/) is an attempt to spread new radionuclides for the development of projects to find new tracer for certain diagnoses. The tracers can be aimed for both diagnostic and treatment purposes. This type of initiative is important since radionuclide production might be a bottle neck for research into future diagnostic and therapeutic methods.

Translational gaps from research to clinical usage

The translation from research to clinical implementation is an important step to make the results from research available for the patients. The translational process is often not smooth or might not even happen. The translation from research to innovations and clinical use is needed to create future health care from today's research.

3. Topics of common interests with European health cluster

The health cluster in Horizon Europe is structured to pillar number 2, global challenges and European industrial competitiveness. Cluster 1 "Health" contains several calls interesting for development of the use of ionising radiation and radiation protection in medicine, even if the announced work programme for 2023 do not contain any specific calls in these areas.

Another interesting part of the Horizon Europe is the Europe's Beating Cancer Plan mission, aiming to beat cancer by 2030. This mission deals with 4 areas: Understanding of cancer, Prevention and early detection, Diagnosis and treatment, and Quality of life for patients and their families. All areas have connections with the rock-n-roll project. Over the financing period several funding opportunities are available in under the Horizon Europe Programme (including the work programmes for missions), the EU4Health Programme, the Digital Europe Programme, the Euratom Programme, and the Interregional Innovation Investments funding instrument. The TGs have identified programmes and topics connected to the respective tasks, which are presented below.

Information about funding & tender opportunities is found at the EC web (<https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-search>).

At the moment, the number of open Horizon Europe calls within the Health Cluster suitable for usage of ionising radiation in medicine and radiation protection is limited.

The Euratom research and training program is active during 2021-2025 and is a complement to the Horizon Europe funding. An overview of the calls can be found here: (https://research-and-innovation.ec.europa.eu/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe/euratom-research-and-training-programme_en)

Task 3.1 Radiation application in oncological diseases: needs and opportunities

The European funding programmes includes several topics with a clear link to Task 3.1. The most important are:

Health cluster

From the 2021-2022 work programme:

HORIZON-HLTH-2021-DISEASE-04-01: Improved supportive, palliative, survivorship and end-of-life care of cancer patients is completely focus on cancer patients.

HORIZON-HLTH-CARE-05-02: Data-driven decision-support tools for better health care delivery and policy-making with a focus on cancer or

HORIZON-HLTH-TOOL-11-02 New methods for the effective use of real-world data and/or synthetic data in regulatory decision-making and/or in health technology assessment.

Additionally, from the 2023-2024 work programme the following calls could be of interest:

HORIZON-MISS-2023-CANCER-01-02: Enhance primary cancer prevention through sustainable behavioural change

HORIZON-HLTH-2023-TOOL-05-03: Integrated, multi-scale computational models of patient patho-physiology ('virtual twins') for personalised disease management

HORIZON-HLTH-2023-TOOL-05-05: Harnessing the potential of real-time data analysis and secure Point-of-Care computing for the benefit of person-centred health and care delivery

Euratom

HORIZON-EURATOM-2021-NRT-01-09 program is also closely related to WP3.1. (European Partnership for research in radiation protection and detection of ionising radiation).

Innovative Health Initiative

HORIZON-JU-IHI-2022-03-01 Screening platform and biomarkers for prediction and prevention of diseases of unmet public health need

EU4Health

From the EU4Health 2022 work programme the following call is of relevance:

CR-g-22-09.01/02/03 Call for proposals to monitor and strengthen the implementation of innovative approaches to prostate, lung and gastric cancer screening at Union level

From the EU4Health 2023 work programme the following calls were identified as relevant for Task 3.1:

CR-g-23-44-01 Call for proposals to support the implementation of the strategic agenda for medical ionising radiation applications (SAMIRA) – organisation of clinical audit campaigns as a tool to improve the quality and safety of medical applications of ionising radiation

CR-g-23-44-03 Direct grants to Member States' authorities: to support implementation of the strategic agenda for medical ionising radiation applications (SAMIRA) – Preparatory activities for a future joint action on quality and safety of medical applications of ionising radiation under the SAMIRA initiative

CR-p-23-39 Evaluation study: Use of sunbeds and cancer risk

CR-p-23-44-02 To support the implementation of the strategic agenda for medical ionising radiation applications (SAMIRA) – study on the implementation of the EURATOM and the Union legal bases with respect to medical devices used in medical applications of ionising radiation

Digital Europe

For the Digital Europe programme, aspects of quality and safety are also relevant, e.g. in the development of algorithms and AI optimisation.

The EU-CAIM project ('EUropean Federation for CANcer IMages') funded under the call DIGITAL-2022-CLOUD-AI-02-CANCER-IMAGE is of interest. The project aims to design and deploy a pan-European digital federated infrastructure facilitating findings and accessing to standardised cancer images and related patient data for basic and clinical research.

Task 3.2 Radiation application in neurovascular diseases: needs and opportunities

For Task 3.2, Horizon Europe topics of relevance in the 2021-2022 work programme are:

Health cluster

HORIZON-HLTH-2022-TOOL-12-01-two-stage: Computational models for new patient stratification strategies

HORIZON-HLTH-2021-STAYHLTH-01-04: A roadmap for personalised prevention

HORIZON-HLTH-2021-DISEASE-04-04: Clinical validation of artificial intelligence (AI) solutions for treatment and care

HORIZON-HLTH-2022-DISEASE-06-04-two-stage: Development of new effective therapies for rare diseases

HORIZON-HLTH-2021-CARE-05-01: Enhancing quality of care and patient safety

HORIZON-HLTH-2021-CARE-05-04: Health care innovation procurement network

HORIZON-HLTH-2022-CARE-10-01: European partnership on transforming health and care systems

HORIZON-HLTH-2021-TOOL-06-03: Innovative tools for use and re-use of health data (in particular of electronic health records and/or patient registries) <

Euratom

The HARMONIC project ('Health Effects of Cardiac Fluoroscopy and Modern Radiotherapy in Paediatrics') has indirect impact (interventional Cardiology and interventional Neuroradiology use similar endovascular techniques and angiosuites, thus similar approach to the use of ionizing radiation) and can be extended to Neurovascular paediatric patients (<https://harmonicproject.eu/>)

The PIANOFORTE partnership is very interesting for Task 3.2 and Interventional Neuroradiology and related medical specialties for the endovascular treatments for Neurovascular diseases should be included (<https://pianoforte-partnership.eu/>).

Task 3.3 Radiation application in cardiovascular diseases: needs and opportunities

Topics from European funding programmes of relevance for Task 3.3 include:

Health cluster

Topics from the 2021-2022 work programme include:

HORIZON-HLTH-2022-STAYHLTH-01-04-two-stage: Trustworthy artificial intelligence (AI) tools to predict the risk of chronic non-communicable diseases and/or their progression

HORIZON-HLTH-2022-STAYHLTH-02-01: Personalised blueprint of chronic inflammation in health-to-disease transition

EU4Health

From the EU4Health 2023 work programme the following call has been identified:

DP-g-22-06.04 and DP-g-22-06.05 Call for proposals on prevention of NCDs - cardiovascular diseases, diabetes and other NCDs

Task 3.4 Identifying radiation application and radiation protection needs and opportunities in other relevant clinical scenarios

Regarding Task 3.4, the following topics are considered relevant:

Health cluster

From the 2021-2022 work programme:

HORIZON-HLTH-2021-STAYHLTH-01-04: A roadmap for personalised prevention

HORIZON-HLTH-2021-DISEASE-04-04: Clinical validation of artificial intelligence (AI) solutions for treatment and care

From the 2023-2024 work programme:

HORIZON-HLTH-2023-TOOL-05-05: Harnessing the potential of real-time data analysis and secure Point-of-Care computing for the benefit of person-centred health and care delivery

Euratom

HORIZON-EURATOM-2021-NRT-01-09: European Partnership for research in radiation protection and detection of ionising radiation

Task 3.5 Addressing common interests and identifying synergies

The Strategic Agenda for Medical Ionising Radiation Applications (SAMIRA) (https://energy.ec.europa.eu/topics/nuclear-energy/radiological-and-nuclear-technology-health/samira-action-plan_en) is a contribution to Europe beats cancer and has three priority areas:

- securing the supply of medical radioisotopes
- improving radiation quality and safety in medicine
- facilitating innovation and the technological development of medical ionising radiation applications

Within SAMIRA several actions are included.

The European initiative PRISMAP is one of the SAMIRA actions – your European provider for medical radionuclides and beyond (www.prismap.eu/) is an attempt to spread new radionuclides for the development of projects to find new tracers for certain diagnoses.

As such, the calls from the EU4Health 2023 work programme related to SAMIRA are of interest (see Task 3.1). Task 3.6 The patient perspective on radiation-based health care and RP research: needs and opportunities

Health cluster

Related to new tools and digital technologies: clear link on the communication aspects (as digital tools have been identified by our Patient Panel as an efficient way to improve clinician-patient risk communication).

Importance of well-being in clinical setting: secure clinical settings have been identified as a way to improve communication.

Euratom

European Partnership for research in radiation protection and detection of ionising radiation: important work on justification of practices and optimisation of radiological protection of patients.

4. Conclusions and recommendations

Even if the clinical fields of medical applications of ionizing radiation, RP, and related research are intense, there is a large need for continuous research in both the use of ionizing radiation and in RP. Several funding possibilities have already been opened via Horizon Europe and it is important that these funding streams continue during the entire period. In Figure 1, the areas where research efforts are needed are summarised with the patient perspective in the center.

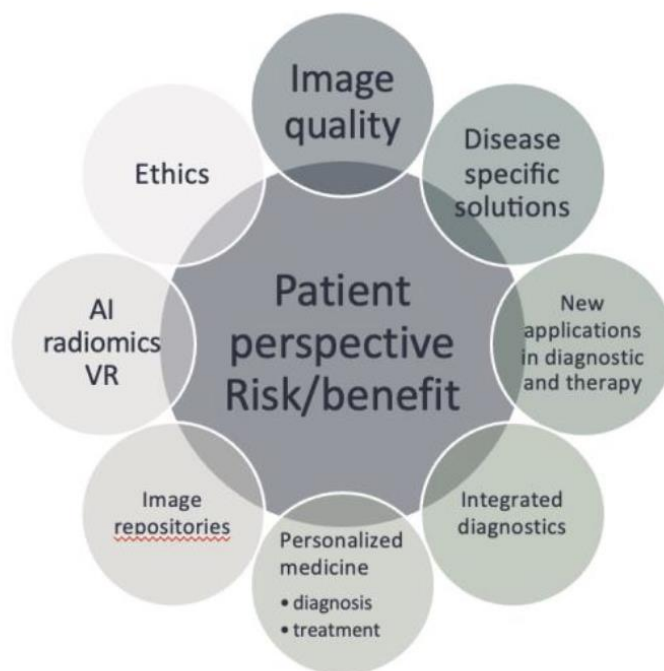


Figure 1: With the patient perspective in focus several areas with need of funding of research is identified.

Figure 1. With the patient perspective in focus several areas with need of funding of research is identified.

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