AIR² Access to INFRASTRUCTURES for Radiation protection Research

Special Issue
January 2018

Editorial

It is a great pleasure to introduce this second special issue dedicated to MEDIRAD, a very ambitious project on the medical use of radiation. After an open preparation process, the coordinators have managed the feat of assembling a multidisciplinary team that includes experts in radiation protection, radiology, radiotherapy, epidemiology, biology, biomedical imaging, and dosimetry. Very promising results are expected. Undoubtedly, there are close links between MEDIRAD and CONCERT that will contribute to improving the development of a joint roadmap for radiation protection.

Dr Laure Sabatier, CEA

The floor to...

I am delighted to be the scientific coordinator of MEDIRAD. I expect this project to be an important step for patient radiation protection. It is exciting in that it brings together motivated and talented experts from many different, but complementary, disciplines (clinical medicine and epidemiology, radiation epidemiology, dosimetry, modelling, and radiation protection and policy).

I have high expectations that MEDIRAD will:

- Increase our knowledge of the health effects of both diagnostic and therapeutic radiation exposure, including the study of individual susceptibility biomarkers.
- Improve the recording and estimation of doses from various procedures, paving the way for future real-time monitoring and dosimetric databases for both clinical practice and epidemiology.
- Help develop evidence-based policies for medical radiation protection.

It is the first time that such an ambitious project is to be conducted!

E. Cardis, ISGlobal
Scientific Coordinator

I was involved in the preparation of the MEDIRAD project from its very beginning and I believe that one major achievement has already been the successful preparation process, as we brought together European medical societies and radiation protection research platforms, as well as basic and clinical medical and nuclear scientists, to focus on a common goal.

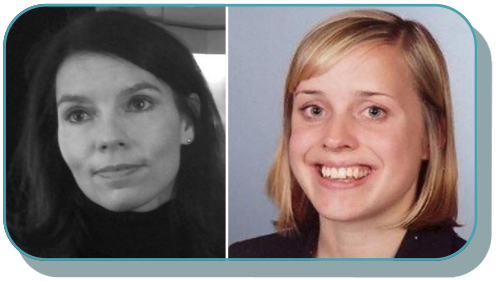
As the clinical coordinator, I am now responsible for the overall clinical management of the MEDIRAD project. In particular, I am supervising the general progress of the project and implementation of the clinical aspects of the work plan. I am also in charge of the ethics management, which is a very important aspect in the MEDIRAD project, as several studies will be carried out. This activity is also supported by an independent ethics advisor who is a member of the Scientific Advisory Board.

I am convinced that the MEDIRAD project will stimulate further radiation protection research and, in particular, strengthen the multidisciplinary collaboration between various disciplines. This will contribute to the identification of new research topics and avoid duplication.

G. Frija, UPDescartes
Clinical Coordinator

Due to the complexity and strong multi-disciplinary character of the MEDIRAD project, the administrative management is separated from the scientific (E. Cardis) and clinical coordination (G. Frija). The European Institute for Biomedical Imaging Research (EIBIR, Austria) acts as coordinator of the project, in charge of overall project management, as well as communication and dissemination activities. EIBIR has a vast and long-standing experience in managing European projects, including numerous research projects and coordination actions under FP6, FP7, and Horizon 2020. In addition, the five medical societies involved in the project's Stakeholder Board are shareholders of EIBIR.

In the MEDIRAD project, we are responsible for contractual and financial management, quality assurance, and risk management, as well as the overall monitoring of compliance with the project plan. Moreover, we are the contact point for the European Commission and provide day-to-day support to all project partners to facilitate efficient internal communication. We are particularly excited about this project as the medical and nuclear sectors join forces for the first time to work together towards the radiation protection of patients and staff.



M. Hierath, EIBIR
Project Coordinator

U. Mayerhofer-Sebera, EIBIR
Project Manager

This project has received funding from the Euratom research and training programme 2014-2018 under grant agreement No 662287

CONCERT CORNER

Future events:

5-8 February 2018
EURADOS AM2018, Lisbon, Portugal

16th February 2018
Stakeholder consultation

20th February 2018
Open Information and Networking Day of the European Radiation Protection Research Platforms, Munich, Germany

21st February 2018
- CONCERT MB Meeting
- Extraordinary and ordinary MELODI EOGA and General Assembly, Munich, Germany

WP 6 News:

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Project Overview-WP1

MEDIRAD: Implications of medical low dose radiation exposure

MEDIRAD (Implications of Medical Low Dose Radiation Exposure) is a multidisciplinary, cross-cutting project funded under the Euratom research and training programme of Horizon 2020. The four-year MEDIRAD project kicked off in June 2017 and is led by the European Institute for Biomedical Imaging Research (EIBIR). The consortium brings together a wide range of expertise, with 33 partners from 14 European countries, and involves research groups that focus on radiology, nuclear medicine, radiotherapy, dosimetry, epidemiology, biology, bioinformatics, modelling, radiation protection, and public health.

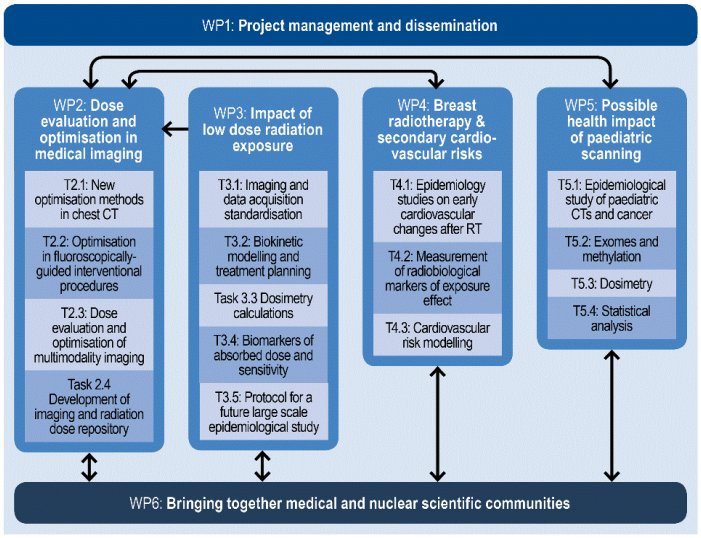

Photo: MEDIRAD project

MEDIRAD work plan

MEDIRAD has three major operational objectives: improving organ dose estimation and registration; evaluating and understanding the mechanisms of the effects of medical radiation exposure, focusing on two outcomes of public health relevance (cardiovascular effects of radiotherapy in breast cancer treatment and cancer risk following CT scanning of children and adolescents); and developing science-based policy recommendations for the effective protection of patients, workers, and the general public. To achieve these objectives, the MEDIRAD project consists of six interdependent and complementary work packages, each of which contains tasks and deliverables vital to the project's success.

MEDIRAD is supported by European medical associations and builds upon existing partnership with the Multidisciplinary European Low Dose Initiative (MELODI), the European Radiation Dosimetry Group (EURADOS), and the European Alliance for Medical Radiation Protection Research (EURAMED). These organisations, together with the World Health Organisation (WHO) and the European Patients' Forum (EPF), constitute the MEDIRAD Stakeholder Board. In addition, a Scientific Advisory Board has been set up with world-renowned experts in the fields of imaging, radiobiology, dosimetry, medical physics, radiation protection, epidemiology, and ethics.

The expected impact of the MEDIRAD project is multifaceted. MEDIRAD will achieve significant progress in the interaction between the radiation protection and medical scientific communities at the EU level, leading to cross-fertilisation of research efforts and the provision of more consolidated and robust science-based policy recommendations to decision-makers in the relevant sectors. The project will also allow better evaluation of the risks from radiation and better quantification of the necessary precautionary measures, leading to a stronger system of protection for patients, workers, and the general public.

MEDIRAD will endeavour to positively modify public perception of risks associated with ionising radiation, thanks to the results of such combined nuclear and medical research. MEDIRAD's long-term impact will lead to new and improved practical measures for the effective protection of people in the medical and nuclear sectors.

Photo: MEDIRAD project

MEDIRAD kick-off meeting in Barcelona, June 2017

MEDIRAD has received funding from the Euratom research and training programme 2014-2018 under grant agreement No 755523.

ID Card:

Project coordinator:
European Institute for Biomedical Imaging Research (**EIBIR**), AT

Partners involved:
- Barcelona Institute for Global Health (**ISGlobal**), ES
- Paris Descartes University (**UPDescartes**), FR

Duration:
48 months

Total budget:
Approx. € 10 Million

Open Access of produced data:
All project results will be made publicly available.

Internet link:
www.medirad-project.eu

Contacts:
Ulrike Mayerhofer-Sebera, MA
European Institute of Biomedical Imaging Research (EIBIR)
Neutorgasse 9
1010 Vienna, Austria
umayerhofer-sebera@eibir.org
+43 1 533 4064-43

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MEDIRAD WP2

Dose evaluation and optimisation in medical imaging

The aim of Work Package 2 (WP2) is to develop novel methodologies to reduce the radiation dose received by patients and staff and potential radiation-related risks of cancer and non-cancer outcomes from chest imaging, while maintaining or improving the diagnostic information from existing and emerging techniques. Work will focus on CT, fluoroscopically-guided interventional procedures, and hybrid systems.

Photo: Foto Maris

Prof. John Damilakis

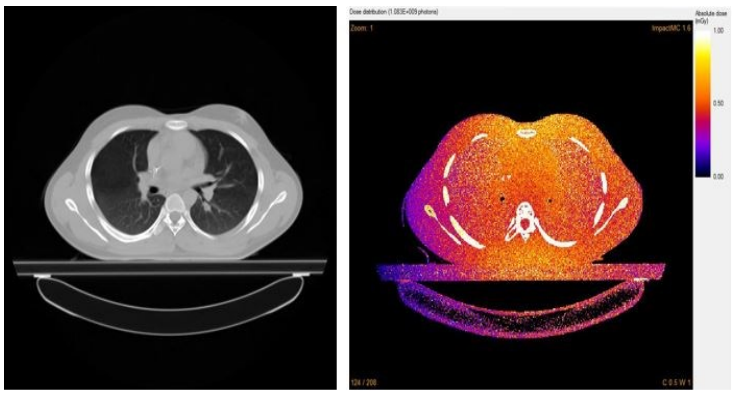

Photo: UoC

A chest CT image (left) and the corresponding radiation dose distribution (right).

Parameters for quantifying image quality are generally measured using standardised phantoms. However, the optimisation of clinical protocols and the prediction of diagnostic performance using phantoms containing standard test objects may be inadequate. Methods are needed to estimate organ and tissue doses based on patient models or detailed voxelised phantoms based on various body statures or models of real patients, representing as many human body anatomies and sizes as possible, and taking into account all parameters that influence patient dose. WP2 will develop a novel tool for the optimisation of patient dose and image information for chest CT, based on the assessment of image quality and detailed spatial three-dimensional (3D) organ and tissue dose distributions from chest-CT examinations.

A state-of-the-art method has been described for dose monitoring for interventional cardiology procedures, based on the accelerated Monte Carlo (MC) code, MC-GPU. The programme has only been tested on several simple, ideal, simulated cardiac procedures, but has not been benchmarked against standard simulation codes, nor tested in the clinical environment. WP2 will provide detailed spatial 3D dose distributions from fluoroscopically-guided ablation procedures for dose optimisation, as well as the optimisation of a novel dose-monitoring system for interventional cardiology procedures and testing of the effectiveness of newly developed tools for brain and eye lens protection of staff who perform fluoroscopically-guided procedures.

There is a strong need for standardisation and optimisation of CT protocols for multi-modality imaging. The establishment and use of Dose Reference Levels (DRLs) in hybrid imaging are required and have been recommended by international organisations. WP2 will perform a European study on the current use of multi-modality systems as a basis for establishing European DRLs for specific applications of CT in PET/CT and SPECT/CT, develop a method for estimating patient organ doses and risks from chest PET/CT and SPECT/CT, and optimise protocols for multi-modality imaging.

A European image and dose repository for benchmarking and research is also needed. In addition, coding is not harmonised in Europe and beyond. WP2 will develop and operate an integrated imaging and dose biobank to address the needs of MEDIRAD researchers (WPs 2-5); develop a common catalogue for names of procedures, clinical symptoms, anatomical locations, and findings; and develop structured reporting templates.

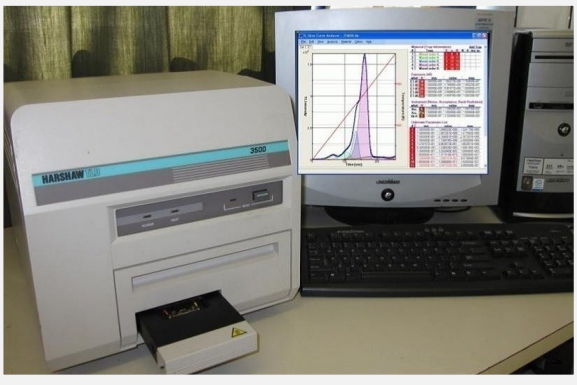

Photo: E. Tzanis/UoC

A thermoluminescent reader system installed at the UoC.

Radiation dose to the conceptus from multidetector CT during early gestation: A method that allows for variations in maternal body size and conceptus position, Damilakis J., Perisinakis K., Tzedakis A., Papadakis A. E., Karantanas A. (2010), Radiology, 257 (2), 483-489

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ID Card:

Leader:
University of Crete (**UoC**), GR

Partners involved:

- Barcelona Institute for Global Health (**ISGlobal**), ES
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- The Royal Marsden National Health Service Trust (**RMH/ICR**), UK
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- Ghent University (**UGENT**), BE
- University Hospital of Wuerzburg (**UKW**), DE
- French National Institute of Health and Medical Research (**INSERM**), FR

Contact:
Prof. John Damilakis
Department of Medical Physics
University of Crete
P.O. Box 2208
71003 Iraklion, Crete, Greece
john.damilakis@med.uoc.gr
+30 2810 392569

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Impact of low dose radiation exposure from ^{131}I radioiodine ablation of thyroid cancer

The overall objectives of MEDIRAD WP3 are to develop and implement the tools necessary to establish, for the first time in a multicentre setting, the range of absorbed doses delivered to healthy organs in patients undergoing thyroid ablation and the threshold absorbed dose required for thyroid ablation. This will enable patient-specific treatment planning that will minimise the risk to the patient while ensuring a successful outcome.

Photo: RMH/ICR

Dr Glenn Flux

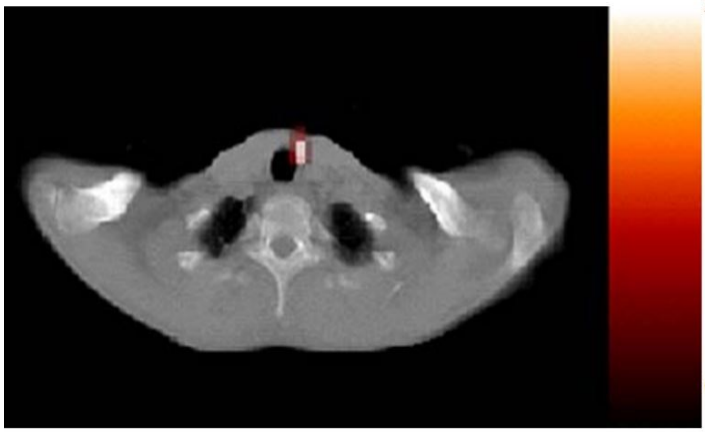

Photo: RMH/ICR

An absorbed dose map overlaid onto a corresponding transaxial slice of the CT scan (Flux et al. 2010).

We will facilitate the development of a large-scale epidemiological study of the effect of low absorbed doses from the irradiation of normal organs by internal radionuclide sources. This will allow individualised risk/benefit treatment planning for these procedures and lead to recommendations and protocols for the calculation of absorbed doses to normal organs from internal I-131 sources, thus facilitating accurate risk analysis in a large population.

To achieve these objectives, we have identified the following aims:

- Gamma camera characterisation for high activity quantitative imaging to enable standardised collation of quantitative image data and absorbed dose calculations obtained at different centres.
- Dosimetry and kinetic modelling will be performed for 100 patients at four sites, to establish the range of absorbed doses delivered to thyroid remnants and to normal organs from fixed levels of administered activity.
- Biomarker studies will be performed to assess individualised radiosensitivities from a subset of patients.
- A database will be developed, in collaboration with WP2, to collect dosimetry and outcome. Within this study the absorbed doses required for successful ablation will be established, and the range of absorbed doses delivered to potential organs-at-risk determined to enable the evaluation of short- and mid-term risk.
- These data will be used to develop personalised risk/benefit dosimetry-based treatment-planning protocols as recommendations for best practice, whereby absorbed doses delivered to organs-at-risk will be minimised while ensuring a successful response.

The methods and tools developed will provide the means to prepare and plan a large-scale study that will evaluate long-term risk from absorbed doses delivered to normal organs and will be translatable to all radionuclides used for diagnostic and therapeutic procedures.

Photo: RMH/ICR

SPECT/CT gamma camera for the acquisition of quantitative imaging data.

ID Card:

Leader:
The Royal Marsden National Health Service Trust (**RMH/ICR**), UK

Partners involved:
- University Hospital of Wuerzburg (**UKW**), DE
- Philipps University of Marburg (**UMR**), DE
- French National Institute of Health and Medical Research (**INSERM**), FR
- Claudius Regaud Institute (**ICR IUCT/-O**), FR

Contact:
Dr Glenn Flux

Joint Department of Physics
Royal Marsden Hospital
Downs Road
Sutton SM2 5PT, UK

glenn.flux@icr.ac.uk

+44 208 661 3485

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MEDIRAD WP4

Breast radiotherapy and secondary cardiovascular risks: Establishing risk models for clinical support

The main objectives of MEDIRAD WP4 are to assess early and mid-term cardiovascular effects after breast radiotherapy (RT) and to develop a time-dependent risk model for these injuries. In addition, prediction models for major cardiac events in the long term will be developed and externally validated to quantify the risk, based on biological and imaging biomarkers for clinically apparent major cardiac events. These prediction models can be used to estimate the impact of various preventive strategies and provide essential information for decision making on the most effective and cost-effective measures.

Photo: E. Kuipers/UMCG

Prof. Rob Coppes

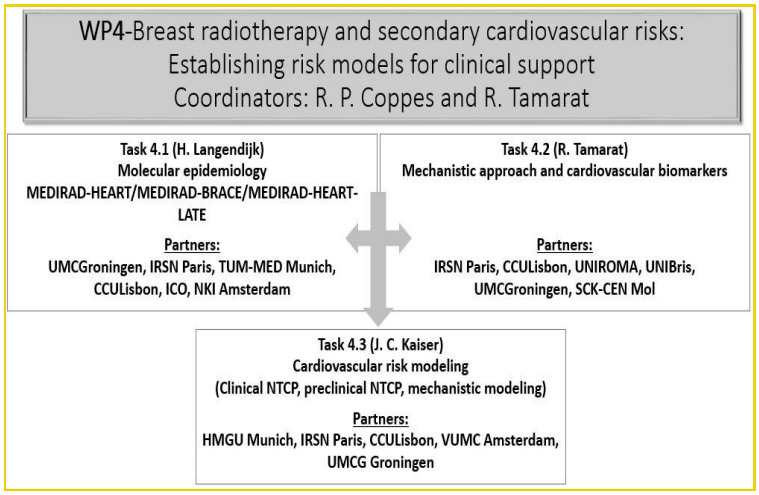

Photo: MEDIRAD project

Tasks of MEDIRAD WP4

The six specific aims of WP4 are to:

- Identify and validate most important cardiac imaging and circulating biomarkers of radiation-induced cardiovascular changes arising in the first two years after breast RT.
- Develop individual risk models (Normal Tissue Complication Probability (NTCP) models) integrating these biomarkers combined with dose metrics of cardiac structures based on 3D-dosimetry.
- Determine the relationship between 3D dose distributions in cardiac substructures and the risk of Acute Coronary Events (ACE) and other cardiac complications in breast cancer patients to develop an externally validated multivariable NTCP model to assess the risk of ACE in individual patients, based on cardiac dose metrics in the first 10 years after breast-cancer RT.
- Investigate the biological mechanisms of heart damage, as a function of dose in rodents, for radiation qualities used in radiology and radiotherapy.
- Define a biomarker profile for cardiac damage induced by low to moderate dose exposure. Identification of relevant biomarkers from preclinical animal studies, validated in humans, will lead to refined models of the risk of cardiac and vascular toxicity after low- to moderate-dose radiation exposure.
- Describe cardiovascular risk by a mathematical model of disease development based on the findings from the above described aims.

WP4 integrates clinical epidemiology, radiobiology, and various modelling approaches to obtain more insight into mechanisms that lead to radiation-induced cardiovascular effects in breast-cancer patients and to develop and validate classical Normal Tissue Complication Probability and mechanistic models to associate low-dose delivery to the heart with a variety of biological, subclinical, and clinical endpoints. The results will contribute to more accurate risk estimations for radiation-induced cardiovascular biological and clinical events and provide potential targets for prevention.

Photo: UMCG

Example of 3D (left) and 2D (right) planning of irradiation plan for breast cancer, showing dose on the heart.

Validation and modification of a prediction model for acute cardiac events in patients with breast cancer treated with radiotherapy based on three-dimensional dose distributions to cardiac substructures, van den Bogaard V. A., Ta B. D., van der Schaaf A. et al. (2017), J Clin Oncol., 35 (11), 1171–1178

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ID Card:

Leader:
University Medical Center Groningen (**UMCG**), NL

Partners involved:

- Paris Descartes University (**UPDescartes**), FR
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- Belgian Nuclear Research Centre (**SCK•CEN**), BE
- Cardiovascular Centre of the University of Lisbon (**CCUL**), PT
- University Hospital rechts der Isar of the Technical University Munich (**TUM-MED**), DE
- Sapienza University of Rome (**SAPIENZA**), IT
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- VU University Medical Center (**VUMC**), NL
- Netherlands Cancer Institute (**NKI**), NL
- Catalan Institute of Oncology (**ICO**), ES

Contact:

Prof. R.P. Coppes

Department of Radiation Oncology
University Medical Center Groningen
University of Groningen
Hanzeplein 1
P.O. Box 30.001
9700RB Groningen,
The Netherlands

r.p.coppes@umcg.nl

+31 503616124

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Possible health impact of paediatric scanning- A molecular epidemiology study

WP5 is devoted to improving our understanding of the potential association between cancer risk and low doses of ionising radiation from CT scans in childhood and adolescence, and to studying the role of factors, including age and genetic/epigenetic variants, which may modify this risk. It builds upon a subset of national studies from the European EPI-CT cohort (http://epi-ct.iarc.fr/) of over 1.1 million patients (Bosch de Basea et al. 2015) and comprises two main studies:

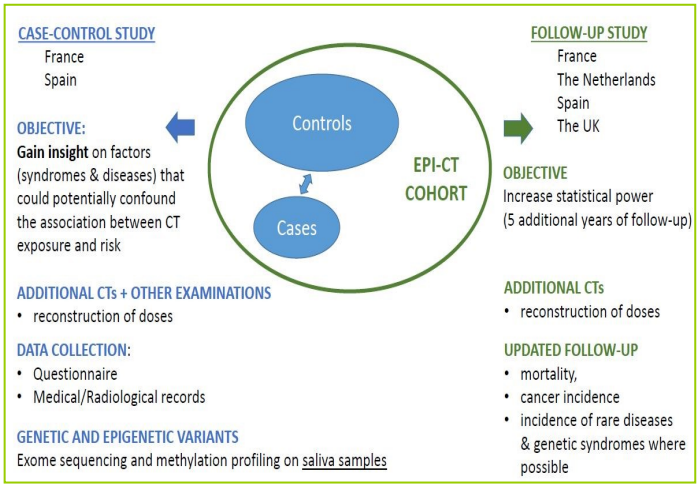

Photo: MEDIRAD project

EPI-CT cohort: Case-control and follow-up study.

1) A *follow-up study*, with an update of the cancer incidence, vital status, and CT scanning data of the largest national cohorts in EPI-CT (from France, the Netherlands, Spain, and the UK). The main objective of the follow-up study is to improve the statistical power for direct estimation of cancer risk compared to the original EPI-CT study and to assess recent changes in CT practices in paediatric radiology. This study is purely record based, with no patient contact.

2) A molecular epidemiological *case-control study* of haematological malignancies and brain tumours nested within the French and Spanish EPI-CT cohorts. This will allow the collection of individual data on other sources of radiation exposure, syndromes, and diseases that could potentially confound any association observed in EPI-CT and the collection of biological samples to study potential markers of radiation sensitivity (exome sequencing and methylation profiling) on a subset of the nested case-control study (Hall et al. 2017).

Activities in the follow-up study, after obtaining ethics approval, will involve updating the CT history of patients already included in the CT cohorts in the participating countries. We will update the follow-up for mortality and cancer incidence, as well as the incidence of rare diseases and genetic syndromes through record linkage with appropriate population and hospital registries, where available. This will provide five additional years of follow-up, increasing the total number of cancers by approximately 7,500, approximately 60% more than those included in the original cohorts, and approximately 25% more leukaemia and brain cancer cases. This will improve the statistical power of the risk analyses.

Photo: ISGlobal

Dr Isabelle Thierry-Chef

In the case-control study, two controls matched for age, sex, and region of residence will be selected per case and a third, matched for radiation dose, to maximise the statistical power to detect genetic/epigenetic-environment interactions. All participants will be contacted, informed about the study, and asked to answer an online questionnaire and give permission for the study investigators to contact their physicians and access medical and radiological records and provide two saliva samples. Exome sequencing and methylation profiling will be performed to identify genetic and epigenetic variants, such as microRNA and lncRNA.

Organ dose estimation following CT exposures will be updated in both studies and in the case-control study, organ doses due to other types of examinations will be estimated.

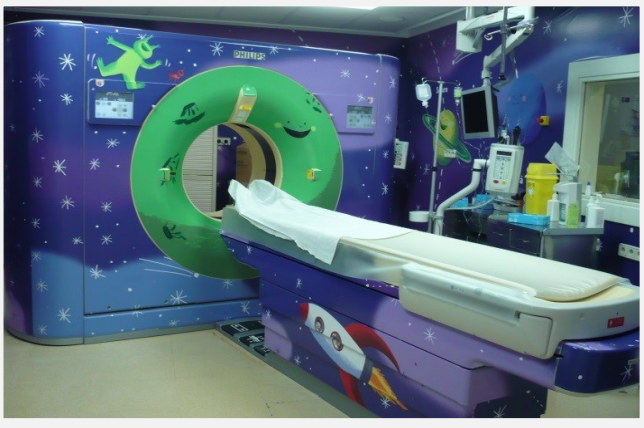

Photo: Hospital Sant Joan de Déu de Barcelona

Hospital Sant Joan de Déu de Barcelona, Spain.

ID Card:

Leader:
Barcelona Institute for Global Health (**ISGlobal**), ES

Partners involved:
- Institute for Radiological Protection and Nuclear Safety (**IRSN**), FR
- Belgian Nuclear Research Centre (**SCK•CEN**), BE
- University of Newcastle upon Tyne (**UNEW**), UK
- Netherlands Cancer Institute (**NKI**), NL
- Autonomous University of Barcelona (**UAB**), ES

Contact:
Dr Isabelle Thierry-Chef
Radiation Programme/ ISGLOBAL
Barcelona Biomedical Research Park Dr Aiguader, 88
08003 Barcelona, Spain
isabelle.thierrychef@isglobal.org
+34 93 2147313

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EPI-CT: design, challenges and epidemiological methods of an international study on cancer risk after paediatric and young adult CT, Bosch de Basea M., Pearce M. S., Kesminiene A., Bernier M. O., Dabin J., Engels H., Hauptmann M., Krille L., Meulepas J. M., Struelens L. et al. (2015), J Radiol Prot., 35 (3), 611-628

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Bringing together medical and nuclear scientific communities to improve patient and worker radiological protection across Europe

The central objectives of MEDIRAD WP6 are to formulate science-based policy recommendations for the effective protection of patients, medical workers, and the general public to decision-makers and practitioners; to organise a web-based consultation of a wide range of stakeholders; and to disseminate the MEDIRAD results to broader communities interested in radiation protection.

The four specific aims of WP6 are to:

- Develop and promote a consensus on standardised procedures, based on the results of WP2, to advocate and facilitate the development of Europe-wide data repositories of patient exposure to ionising radiation (dosimetric information, imaging records) for the purpose of optimising medical protocols and facilitating further research on low-dose effects.

- Develop and promote consensus recommendations on the optimised medical use of ionising radiation, based on the findings of MEDIRAD WP2, WP3, WP4, and WP5, and disseminate relevant information among clinicians, radiologists, radiographers, nuclear medicine physicians, and medical physicists.

- Develop and promote consensus recommendations towards enhancing the robustness of the European radiation protection system, based on the findings of the MEDIRAD WP's and the lessons learned from a web consultation of a wide range of stakeholders, in the context of the implementation of Council Directive 2013/59/Euratom (the revised European BSS Directive).

- Disseminate relevant information about MEDIRAD results to the concerned scientific communities, both in the medical and nuclear sectors, to further bring them together, as well as to competent authorities, and contribute to the continuous elaboration and updating of Strategic Research Agendas (SRAs) and associated roadmaps relevant to radiation protection research in Europe.

MEDIRAD WP6 will set up a Stakeholder Board (SHB), as well as a Stakeholder Forum (SHF), to facilitate the stakeholder consultation.

Photo: IRSN

Dr Jean-René Jourdain

The SHB will consist of a group of experts, bringing together one representative from each of the following organisations: MELODI (Multidisciplinary European Low Dose Initiative), EURADOS (European Radiation Dosimetry Group), EURAMED (European Alliance for Medical Radiation Protection Research, ESR (European Society of Radiology), ESTRO (European Society for Radiotherapy & Oncology), EANM (European Association of Nuclear Medicine), EFRS (European Federation of Radiographer Societies), EFOMP (European Federation of Organizations for Medical Physics), EPF (European Patients' Forum), and WHO (World Health Organization).

The Stakeholder Forum will consist of a maximum of 150 stakeholder representatives who will be invited to answer the web-consultation that SCK•CEN will implement with the objective of consulting stakeholders on the content of recommendations that will be developed within MEDIRAD WP6.

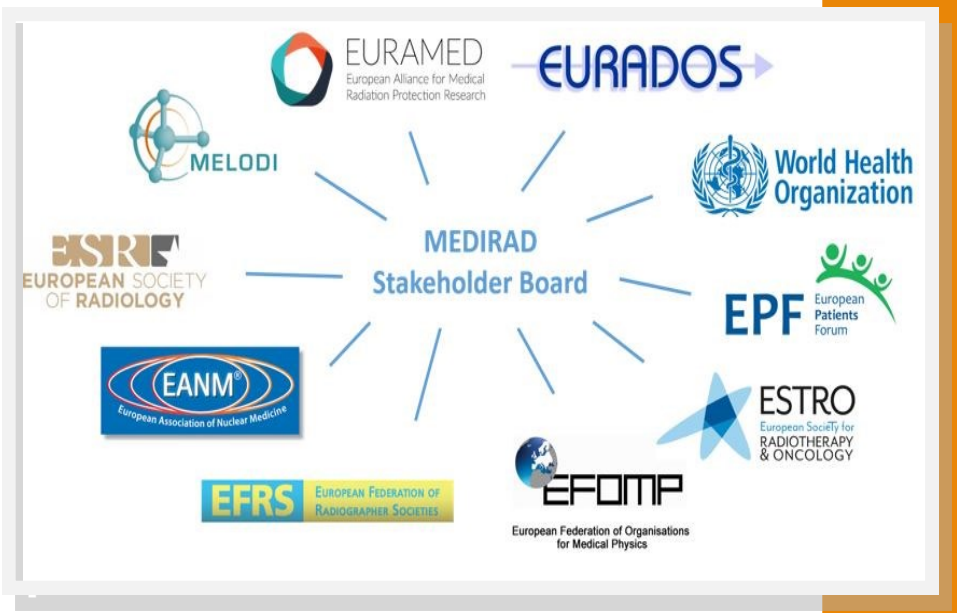

Photo: MEDIRAD project

MEDIRAD Stakeholder Board

ID Card:

Leader:
Institute for Radiological Protection and Nuclear Safety (**IRSN**), FR

Partners involved:

- European Institute for Biomedical Imaging Research (**EIBIR**), AT
- Barcelona Institute for Global Health (**ISGlobal**), ES
- Belgian Nuclear Research Centre (**SCK•CEN**), BE
- Italian National Institute of Health (**ISS**), IT
- University College Dublin, National University of Ireland (**UCD**), IE

Contact:
Dr Jean-René Jourdain
International Affairs Directorate
IRSN
31 avenue de la division Leclerc
F-92260 Fontenay-aux-Roses, France
jean-rene.jourdain@irsn.fr
+33 1 58 35 87 67

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