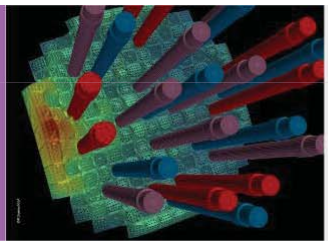


MEDICAL APPLICATIONS OF IONIZING RADIATION AND RADIATION PROTECTION FOR EUROPEAN PATIENTS, POPULATION AND ENVIRONMENT

Isabelle Thierry-Chef[1,2,3], Elisabeth Cardis[1,2,3], John Damilakis[4], Guy Frija[5], Monika Hierath[6], Christoph Hoeschen[7] on behalf of the HARMONIC, MEDIRAD, SINFONIA and EURAMED rocc-n-roll consortia members.

[1]Barcelona Institute of Global Health (ISGlobal), [2]University Pompeu Fabra,[3]CIBER Epidemiologia y Salud Pública, Spain
[4]University of Crete, Greece, [5]Université Paris Descartes, France, [6]EIBIR gemeinnützige GmbH, Austria,[7]Otto-von-Guericke University, Germany

INTRODUCTION

- Medical applications of ionizing radiation (IR) play a crucial beneficial role in
  - efficient health care
  - diagnosis and treatment of many diseases.
- Represent the largest man-made source of radiation exposure to the population
- Risks are associated with ionizing radiation (cancer and non-cancer effects).
- it is particularly important to optimize their use and the doses they entail.

EURATOM FUNDED PROJECTS

EURATOM has funded four large-scale projects in the last 6 years

MEDIRAD Harmonic SINFONIA EURAMED ROCC-N-ROLL

to:

- improve estimates of the detrimental effects of medical applications;
- provide evidence-based input and new approaches to optimize their use and the resulting doses;
- improve benefit of medical applications of IR and reduce associated risks to patients and medical professionals; and
- ultimately provide evidence for further updating of the current BSS.

OVERALL OBJECTIVES

The projects contribute in a complementary fashion to

- optimizing medical applications of IR;
- improving our understanding of radiation effects; and
- generating evidence-based recommendations both for research and for clinical practice to the main stakeholders

They are particularly pertinent to the issue of RP in medicine

They cover the most important sources of diagnostic and therapeutic medical radiation to

patients

especially children

and workers

Implications of Medical Low Dose Radiation Exposure

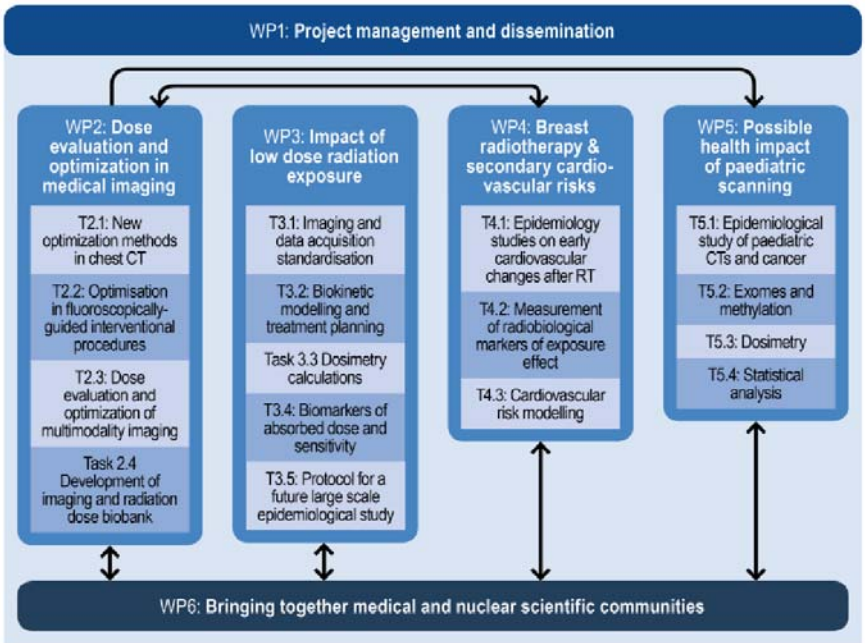
MEDIRAD

Key research objectives summarised in 3 pillars

- **Pillar 1:** Development of innovative tools to increase the efficiency of future radiation protection research activities and support good clinical practice.
- **Pillar 2:** Improvement of the understanding of low-dose ionising radiation risks associated with major medical radiation procedures.
- **Pillar 3:** Development of recommendations based on research results and establishment of information exchange infrastructure to facilitate consensus.

http://www.medirad-project.eu/

MEDIRAD



Diagnostic and therapeutic applications

- Diagnostic:
  - chest CT & Multimodality imaging
  - pediatric CT scanning
- Fluoroscopy : patients and staff
- Radiotherapy:
  - Breast cancer RT
  - Radioactive iodine for thyroid cancer

Multidisciplinarity of the team

- Clinicians (pediatric oncologists, radiation oncologists, cardiologists, radiologists)
- epidemiologists and biologists
- medical physicists
- sociologists

+ patients & regulators in stakeholder group.

MEDIRAD Key Scientific Results

Image quality and doses

- Tool to determine image quality to maximise optimisation of RP in medical imaging;
- First European imaging and dose repository;
- Standardised quantitative I-131 imaging for dosimetry;
- Dose calculation tools for CT scanning and molecular radiotherapy;

Biomarkers

- Identification of important cardiac imaging and circulating biomarkers of radiation-induced cardiovascular changes after breast RT;
- Identification of potential biomarkers of susceptibility to low-dose RIC*.

RIC: Radiation Induced Cancer

MEDIRAD Key Scientific Results

Risk estimation

- Prediction model to assess risk of acute coronary events after RT in individual breast cancer patients, based on 3D cardiac dose distributions;
- New multinational cohorts of breast cancer patients:
  - To investigate cardiac changes arising in the first 2 years after RT
  - To investigate long term cardiac complications of RT
- Extended follow-up of key European paediatric-CT cohorts
  - To refine estimates of radiation induced cancer risk

MEDIRAD RECOMMENDATIONS

1. CONSOLIDATION OF PATIENT DATA REPOSITORIES ACROSS EUROPE
2. OPTIMISATION OF RADIATION-BASED PROTOCOLS FOR MEDICAL DIAGNOSTICS OR THERAPY
3. FURTHER OPTIMISATION OF RADIATION PROTECTION FOR PATIENTS AND MEDICAL WORKERS
4. FUTURE RESEARCH ON MEDICAL RADIATION PROTECTION IN EUROPE

HARMONIC

In **therapeutic use** of ionising radiation, benefits to the patient largely outweigh the risk

However, late effects of exposure are important to understand in children with increased survival

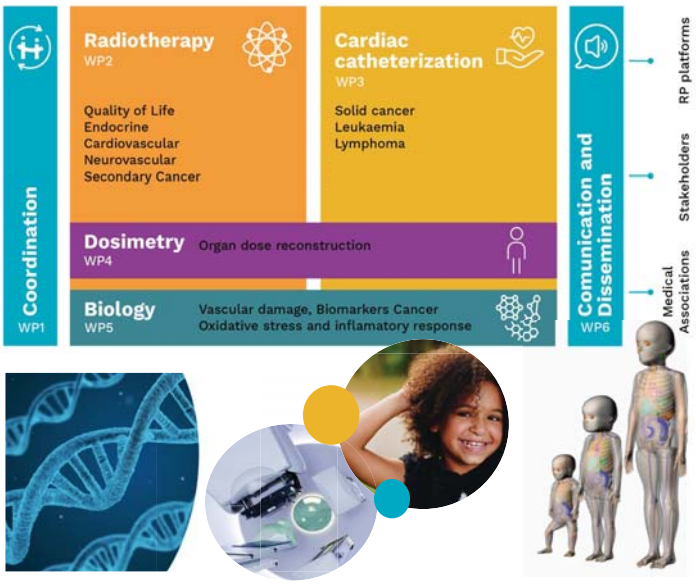
Objectives

Better understand the long-term health effects of medical exposure to ionising radiation in children:

- Cancer patients treated with modern radiotherapy modalities
- Cardiac patients treated with X-ray guided imaging procedures

HARMONIC

Organisation



Cohorts

Radiotherapy

CENTER	RETROSPECTIVE INCLUSION TIME PERIOD	RETROSPECTIVE INCLUSION No. PATIENTS	PROSPECTIVE INCULSION TIME PERIOD	PROSPECTIVE INCULSION No. PATIENTS	TOTAL
KU Leuven	2008-2020	320	2021-2023	90	410
Aarhus	na	0	2021-2023	**18**/90	90
Baclesse	na	0	2021-2023	90	90
G. Roussy	2013-2020	380	2021-2023	180	560
UK Essen	2013-2020	**330**/1140	2021-2023	**16**/360	1500
OVERALL		1840		810	2650

In blue, are centers including photon therapy patients

In bold, are numbers of patients already included (as of April 5th 2022)

Cardiology

COUNTRY	AGE (YEAR)	START OF ACCRUAL & FOLLOW-UP	NUMBER OF HOSPITALS	END OF ACCRUAL	END OF FOLLOW-UP	ALREADY IN	EXPECTED COHORT SIZE
BELGIUM	0-18	2004	3	2020	2020	1341	6,000
FRANCE	0-16	2000	15	2013	2016	18600	19,000
GERMANY	0-18	2004	2	2020	2020		4,000
	0-18	2004	health care database	2020	2018		30,000
ITALY	0-18	2017	2	2021	2022	384	1,000
NORWAY	0-18	1975	1 (Oslo)	2022	2022	4817	6,000
SPAIN	0-21	1995	1 to 2	2021	2020		5,000
UK	0-22	1991	6	2020	2020	20464	30,000
						~45600	~100,000

SINFONIA

Objective

The main objective of the 4-year SINFONIA project is to develop novel methodologies and tools that will provide a comprehensive risk appraisal for detrimental effects of radiation exposure on patients, workers, carers and comforters, the public and the environment during the management of patients suspected or diagnosed with lymphoma and brain tumours.

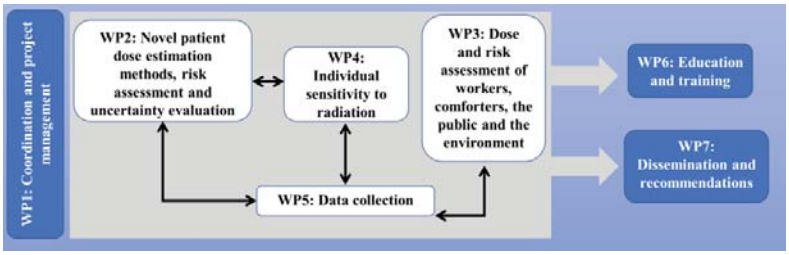
Specific Objectives

- Development of innovative AI-powered tools for quick and accurate estimation of organ doses from X-ray and nuclear medicine examinations
- Risk appraisal of radiation-induced malignancies
- Development of a novel framework to estimate personalised organ-specific dose from scatter radiation in photon-based radiotherapy, neutron-radiation and imaging in radiation therapy

SINFONIA

Specific Objectives

- Dose and risk assessment of staff, comforters, the public and the environment
- Establishment of the extent of variability in radiation sensitivity between patients and development of biomarkers to identify patients susceptible to radiotherapy-induced second malignant neoplasms
- Development of a data repository for imaging and non-imaging data and deployment of the AI models
- Recommendations and education and training



Main results so far:

Please visit

SINFONIA's poster

EURAMED Rocc-n-roll

- EURAMED rocc-n-roll is a coordination and support action project (running from September 2020 to August 2023) initiated to develop a strategic research agenda (SRA) for medical applications of ionizing radiation and the corresponding radiation protection as well as a corresponding roadmap.
- This will be developed by a consortium of 29 partners and a large advisory board trying to take into account the ideas and opinions of all relevant stakeholders. To guarantee that many publicly available workshops will be held.
- The SRA and roadmap will fit in for example into the SAMIRA action plan by the EC as well as the Europe's Beating Cancer Plan
- The SRA will include and be partly based on aspects of the MEDIRAD recommendations and the results of the other three projects. The idea will be to develop a SRA focussed on a patient-centred approach.

EURAMED Rocc-n-roll

- The current approach for the structure of the SRA looks like this:

Abstract
Keywords
Introduction
1. Medical challenge and corresponding research needs (21 pages max)
2. The corresponding Radiation Protection approaches (27 pages max)
3. Organisational requirements and corresponding research (19 pages max)
Conclusion (1 page max)
Summary list of proposed research topics and measures (max 3 pages)
References

Multidisciplinatity of the team

- Clinicians (pediatric oncologists, radiation oncologists, cardiologists neuroradiologists, nuclear medicine specialists, radiologists),
- epidemiologists,
- biologists,
- iT experts,
- medical physicists,
- physicists from nuclear research sites
- social scientists,
- patients / patient representatives,
- Regulators
- Representatives of radiation protection organisations

CHALLENGES

Maximise benefits & minimise potential adverse effects of IR exposure:

- More research than ever is needed regarding potential benefits to patients given the growing use of medical applications of ionising radiation;
- It is crucial to develop **interdisciplinary approaches** between
  - the radiation protection community
  - the health community
  - the digitization community,

  especially when referring to the rapid developments and new possibilities improving patient care harmonized within Europe.
- There is an urgent need for developing **European-wide**
  - interconnected dose, imaging and biological data repositories
  - sustainable infrastructures for long-term clinical epidemiological patient follow-up

IMPACTS

- Our four projects impact radiological protection in the medical community by
  - developing improved dosimetry and optimization tools to provide, in real time, more accurate and personalised dose assessment
  - conducting more precise estimation of the dose-risk relationship for the benefit of the patients, staff and the general population.
- The RP and medical communities are joining forces to understand the relationship between ionising radiation exposure from diagnostic and therapeutic procedures and risk of cancer and non-cancer effects in specific populations
- Research on biomarkers of sensitivity to identify patients with potential higher risk of short, medium or long-term radiation induced effects and improve patient-care on an individualised medicine basis.

CONCLUSIONS

- The four EU projects rely on interdisciplinary consortia:
  - partners from different regions to integrate regional differences,
  - close collaboration between the different disciplines to achieve reliable and meaningful results.
- Results have the potential to be transferred into clinical practice and daily medical use:
  - easy applicable tools
  - education and training recommendations.
- Research on medical applications of ionizing radiation and radiation protection has a great potential for better and safer healthcare for the individual patients.
- Further research, into new applications, to improve medical care and the quality of life of patients is necessary.
- Special consideration needs to be given to data protection, especially taking into account the potential benefits of safely used AI applications in radiation-based medicine.

Thank you for your attention !

On behalf of the Consortia: