



OPERRA

OPEN PROJECT FOR EUROPEAN RADIATION RESEARCH AREA

The OPERRA Project and First Call

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OPERRA Project Coordinator



Concept & Main Objectives

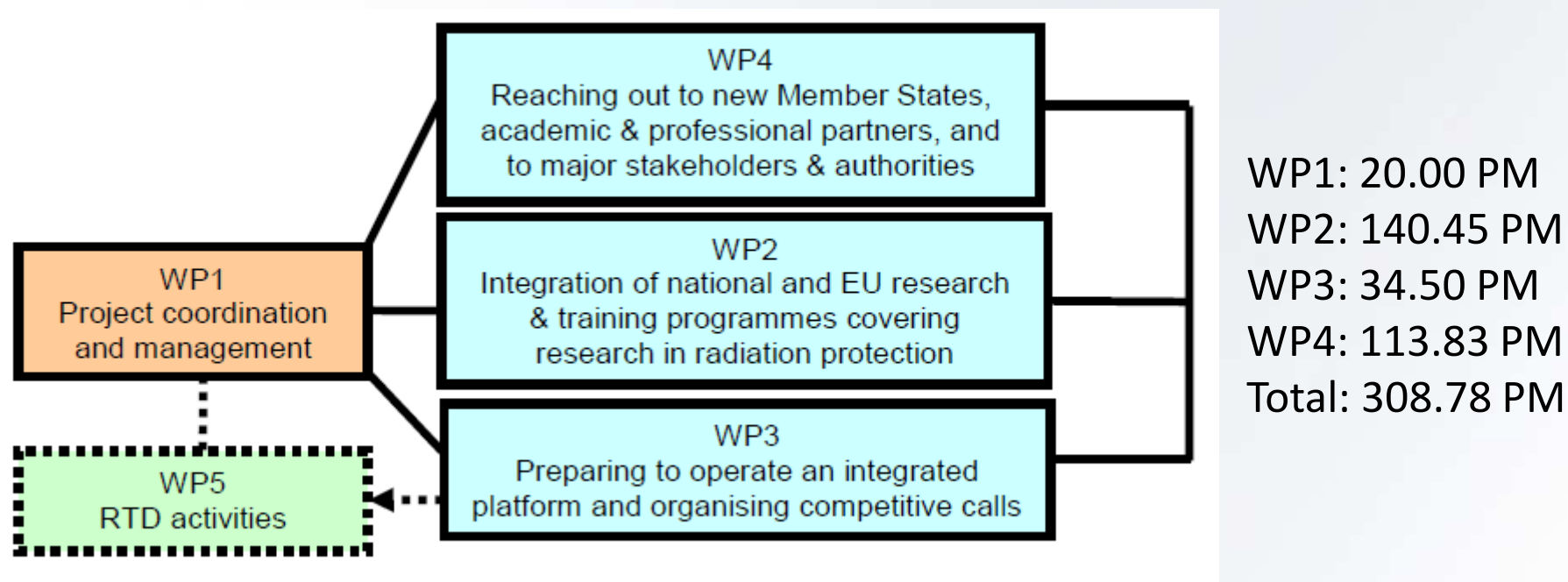
- To build up an umbrella coordination structure that has the capacity in a legal and logistical sense to administer future calls for research in radiation protection on behalf of the European Commission
- The MELODI Association will take the lead with the support of sister structures as equal partners (e.g. Alliance, NERIS, EURADOS, EURAMET, EUTERP, etc.)



Overall Strategy

- The OPERRA project aims at developing a Joint Programming European Instrument describing the actions to be implemented for:
 - Setting-up a sustainable organisation governing radiation protection research, including education and training issues, in Europe (WP3)
 - Organising research calls in radiation protection (WP3)
 - Engaging the key partners in radiation protection as well as national & international funding agencies (WP2)
 - Reaching out to universities & academic partners, new EU Member States, major stakeholders & authorities as well as other technical platforms within and outside of EURATOM (WP4)

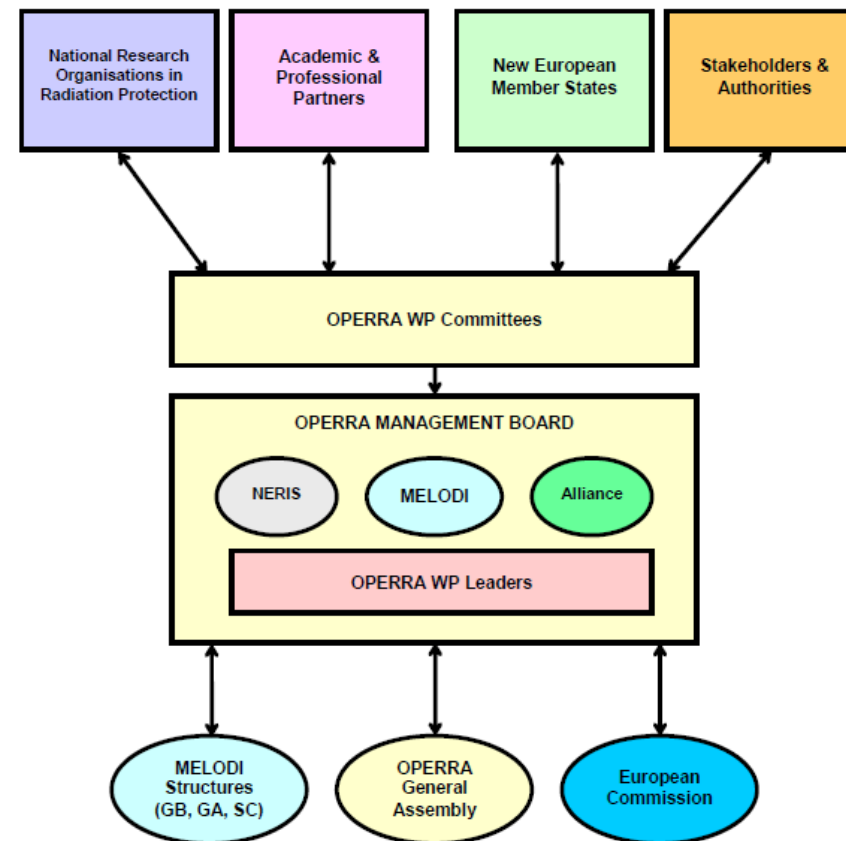
Relationships between Work Packages



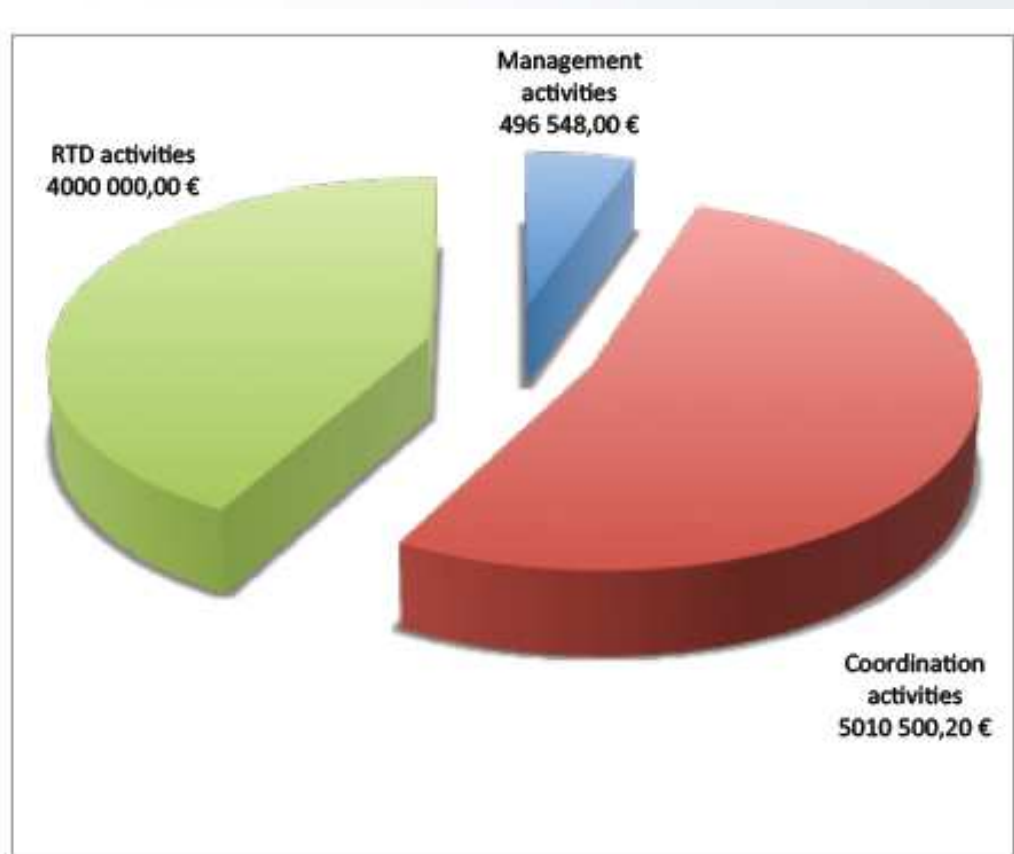
Duration of the Project: 48 Months

WP Leaders: IRSN (WP1), BfS (WP2), MELODI (WP3), STUK (WP4)

Decision-making Structure



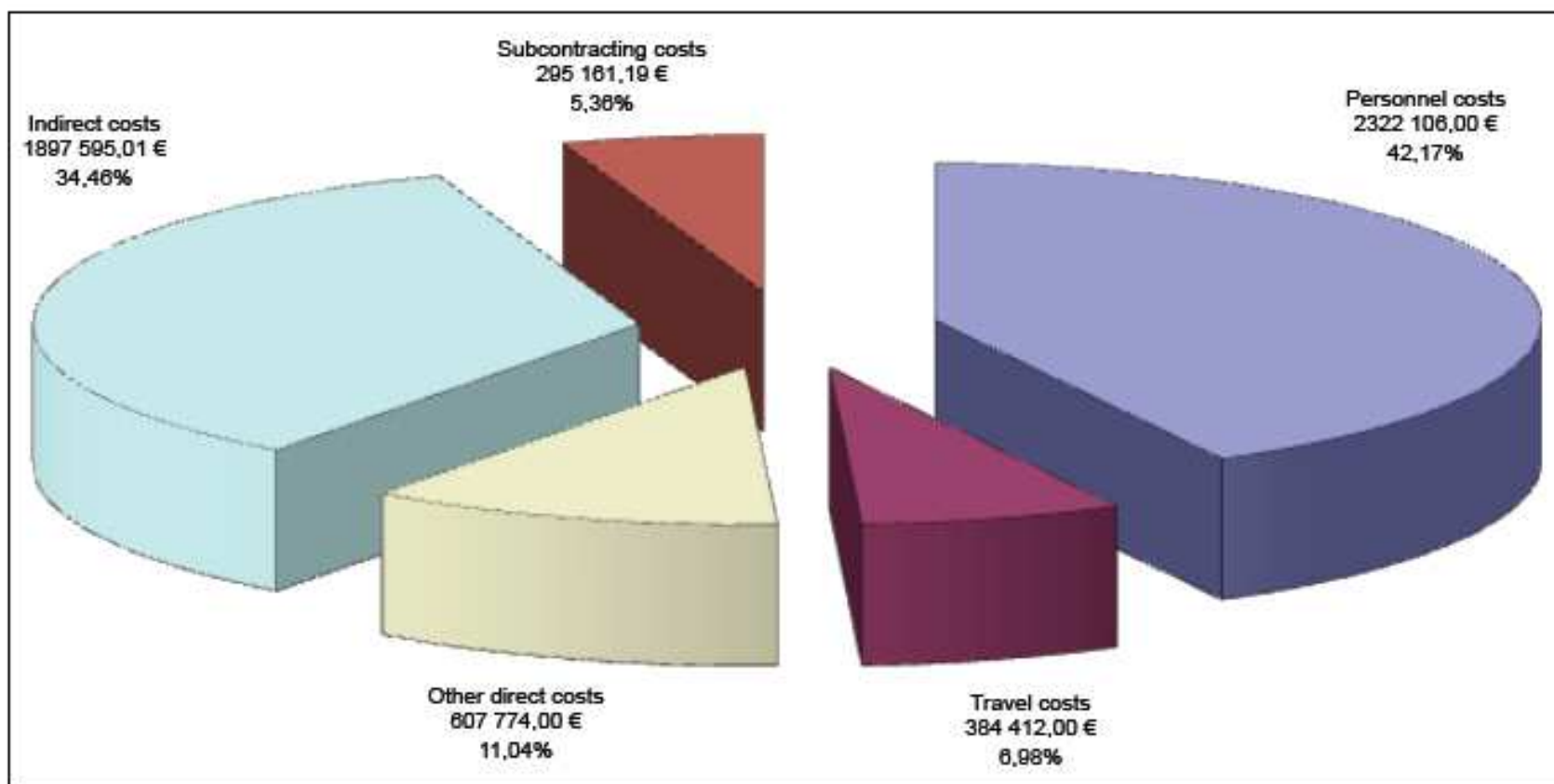
Total Eligible Costs per Activity Type



Total Costs
9,507,048.20 €

EC Contribution
8,000,000.00 €

Eligible Costs per Cost Category





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**WP2: Integration of national and EU
research and training programmes
covering research in radiation protection**

Lead: Thomas Jung (BfS, Germany)



SRAs, Priorities and Road Maps

- Platforms and organizations should be encouraged to develop and maintain their own SRAs, priorities and road maps
- Beside research topics SRAs should include E&T
- OPERRA should develop a view on joint programming, priority setting and road map development for RPR as a whole, by building on existing SRAs from platforms/organizations and by making use of the synergisms of intra, inter and extra platform/organization discussions



SRAs, Priorities and Road Maps

- WP2 will start work on joint programming by identifying relevant international platforms and organizations (Task 2.1) and national institutions as well as national funding organizations (Task 2.2)
- Procedures to start thematic joint programming will be developed together with the relevant partners identified (Tasks 2.3-2.6)



Task 2.1 - Identifying key partners involved in RP research, and E&T, and joint programming of research activities in RP: links with MELODI, ALLIANCE, NERIS, EUTERP, EURADOS & EURAMET

- Existing integration mechanisms in the different research platforms will be analyzed and the potential for collaboration will be explored. Joint programming of radiation protection research will be promoted as well as integration of education & training activities with research activities in all areas of radiation protection research
- To this end, close collaborations between the existing radiation research platforms will be established. A joint strategic research agenda (SRA) and road map (RM) for radiation protection research in Europe will be developed. The specific traditions and identities within the scientific disciplines will be respected as long as the main goal of joint programming is the driving force. Key partners for joint programming in research as well as education & training will be engaged



Task 2.2 - Determining joint funding mechanisms for national & EU Fission R&D programmes

- Aim is to firstly elucidate ways of joint programming and funding of radiation protection research in Europe to meet the strategic goals as described by HLEG and MELODI. In a later step agreed ways of joint programming and if possible funding will be ascertained
- Two options:
 1. On the basis of the joint programming, shared funding responsibilities have to be discussed and agreed on between relevant bodies in Europe and MS in a way that specific parts of the program are funded by Europe and other parts by national funding agencies. For this option, it must be clear from the very beginning that the projects with the joint programming will be closely linked to each other
 2. On the basis of joint programming, national funding agencies will give a defined portion of their available budget to the new umbrella organization to better coordinate European and national funding



Task 2.3 - Identifying experiences and lessons learned from existing exposure situations, including Chernobyl, Fukushima, and the NORM industry

- Existing exposure situations from natural radioactive sources or after a major nuclear accident are major challenges for radiation protection in general and targeted research in particular
- Experience from existing exposure situations will be gathered and lessons learned from emergency response, remediation measures and health impact will be described. Based on this, research needs to improve preparedness for future accidents and to optimize radiation protection measures for exposure remediation will be identified. They will be prioritized with regards to health impact:
- There will be three subtasks:
 - Subtask 2.3.1: Emergency situations
 - Subtask 2.3.2: Remediation
 - Subtask 2.3.3: Health impact



Task 2.4 - Exploring how to enhance radiation protection research activities related to the medical uses of ionizing radiation

- Best strategies to optimize medical exposures will be developed by integrating knowledge from radiation protection and medical professionals and by identifying research, education and training priorities to improve radiation protection in medicine
- Subtask 2.4.1: "High dose" procedures based on X-ray imaging (CT, angiography)
 - The aim of the workshop to be organized within this subtask is to decide in which direction European research should go to have an important impact on radiation protection for staff and patients
- Subtask 2.4.2: Nuclear medicine procedures
 - The aim of this subtask would be to gather information about hitherto performed investigations. The workshop to be held is aimed at deciding on future research directions
- Subtask 2.4.3: Therapeutic procedures
 - The effectiveness of radiation therapy types in terms of tumor curing and reducing late health effects (like secondary cancers) is not investigated for many applications so far. Within this task, a workshop will decide on the future research to be performed in this field



Task 2.5 - Preparing the migration from DoReMi, STAR & NERIS-TP

- Existing NoEs in RP research have established successful methods to promote radiation protection research by
 - Contributing to SRA development
 - Infrastructure and knowledge management
 - Engaging wider scientific community
 - Organizing internal and competitive calls
- Good practices need to be migrated to the new platform to be established in WP3
- This task will perform an evaluation of methodology development for the TRA process and make recommendations for best practices for future program development
 - How input data for TRA development was obtained and what the best practises had been?
 - How topics for internal and competitive calls were identified?
 - How relevance, potential impact and feasibility of approaches was evaluated?
 - How external consultation was searched?



Task 2.6 - Integrating knowledge from non-radiation research

- This task will explore expertise gathered in other fields of research, not directly related to radiation protection research, with a view to strengthening the exchange and integration of knowledge between the radiation and non-radiation research communities
- For this, Task 2.6 will organize small workshops with scientists from outside and inside the radiation community in order to identify knowledge and infrastructures that can be applied to radiation research, thus optimizing resources for the future, and drawing on outside expertise and avoiding re-inventing the wheel where it exists.
- By bringing together relevant experts in thematic workshops (Review of existing European non-radiation cohorts, molecular epidemiological approaches, lessons from stem cells and animal models outside the radiation field, biomarkers/molecular biology (including proteomics), integrative biology including systems biology and biochemistry, modeling of pathogenesis), a roadmap will be developed for the integration of knowledge in epidemiology, biology, biostatistics, bioinformatics, biochemistry and physics from outside



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WP3: Preparing to operate an integrated platform & organizing competitive calls

Lead: Jacques Repussard (MELODI Association)



Main Objectives of OPERRA WP3

- To build up an umbrella coordination structure that has the capacity in a legal and logistical sense to administer future calls for research in radiation protection as a whole (including low-dose risk, radioecology, nuclear emergency management, and also research activities related to the medical uses of ionising radiation) on behalf of the European Commission
- To organise a first competitive call for projects in low-dose risk research (2013) and a second competitive call for broader projects in radiation protection research (2014), subject to the approval of EC services



Setting-up a European Umbrella Structure for Radiation Protection Research Call Administration

- The OPERRA Project aims at bringing the MELODI Association, with the support of its sister structures, to the level of managerial, legal, administrative and financial maturity required to implement the preparatory phase for the development of a federating body
- The OPERRA project will elaborate a draft European Joint Programming Instrument describing the operational function of an umbrella structure as a federating body, structuring and organising radiation protection research in Europe
- This task will get benefit of consensus seminars bringing together representatives of research organisations, universities, national competent authorities, stakeholders, and non-EU countries: the draft instrument should be applicable to the other fields of radiation protection



Setting-up a European Umbrella Structure for Radiation Protection Research Call Administration

- The OPERRA Project will prepare draft documents describing the statutory and internal rules of decision-making structures, management structures, external advisory board (involving other partners, e.g. HERCA, European Society of Radiology, Third Countries, etc.) as well as of inter-governmental agreements that may be necessary at a later stage
- A document describing how the MELODI Association, with the support of its sister structures, will manage and justify its liability for the European funds that would transit, through MELODI, from the EC to all research partners concerned will also be elaborated
- The OPERRA Project will define financial arrangements for the coordination and integration of national R&T efforts through national and translational public-public partnerships



Setting-up a European Umbrella Structure for Radiation Protection Research Call Administration

- The OPERRA Project will study alternative mechanisms through which innovative R&T approaches, including infrastructures, may be funded in complement
- The OPERRA Project will plan, over a period of at least ten years, the conditions for progressive integration of the national R&T efforts, and describe indicative timetables for future radiation protection research calls (call drafting, submission, evaluation, negotiation, etc.)
- The OPERRA Project will estimate and define timing of human & financial resources needed to manage the MELODI Association as an umbrella organisation governing research calls in radiation protection at the European level
- The OPERRA Project will examine the options of including these resources inside MELODI, or in a subcontracting system according to periodic tendering contracts



Supporting the organisation of competitive calls for radiation protection research

- The GAO will organise the evaluation process. The evaluation of the responses to the call will be done by experts selected for appropriate skills and independence, from the database of experts currently operated by the EC
- The GAO will ensure that the evaluation process is conducted anonymously, with respect to the OPERRA and project partners, including MELODI
- The evaluation summary reports will be transmitted by the GAO to the OPERRA Coordinator. On the basis of the evaluation summary reports and the ranking list of the proposals, the OPERRA MB will make final decision of the proposals to be funded
- The OPERRA Coordinator will then perform the necessary actions to include new beneficiaries in the consortium or allocate additional funding to existing members, inform the EC of the results of such activities and prepare amendment of the OPERRA GA to include new members in the consortium



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**WP4: Reaching out to new Member States,
academic & professional partners,
stakeholders & authorities**

Lead: Sisko Salomaa (STUK, Finland)



WP4 Main Objectives

- To ensure the involvement of all other actors, aside from those clearly identified as already playing a central role, who may also contribute to defining the future research priorities in radiation protection
- To benefit from all resources that may serve the interests of the European radiation protection community



WP4 Detailed Objective #1

- To explore how the potential of academic & professional institutions can be integrated to strengthen their role in radiation protection research, and
- To take advantage of their experience in social & human sciences (e.g. risk communication, risk perception, ethics)



WP4 Detailed Objective #2

- To undertake coordination activities to remove the barriers that inhibit the involvement of the new EU Member States in radiation protection research



WP4 Detailed Objective #3

- To encourage an active dialogue with all parties at the national & international level with a significant interest in radiation protection
- To ensure that the research prioritized by key platforms (MELODI, Alliance, NERIS and EURADOS) is directed towards issues of concern to major stakeholders & authorities



WP4 Detailed Objective #4

- To maximize the use of and access to Europe-wide research infrastructures within and outside the radiobiology community
- To reach out to and integrate with flagship projects of the EC, ESFRI, and major networks of excellence outside of radiobiology and radiation protection



WP4 Detailed Objective #5

- To dialogue and cooperate with other technical integrated platforms (e.g. SNE-TP, IGD-TP) paving the way for Horizon 2020 within EURATOM



WP4: Reaching out to new Member States, academic & professional partners, stakeholders & authorities

- Task 4.1 - Reaching out to universities & professional partners (lead: JU, Friedo Zoelzer)
- Task 4.2 – Reaching out to and integrating new Member States (lead: OSSKI, Géza Sáfrány)
- Task 4.3 – Reaching out to major stakeholders & authorities (lead: HPA, Simon Bouffler)
- Task 4.4 – Interactions with ESFRI platforms & large EU consortia to support research in the field of radiation protection (lead: CEA, Paul-Henri Roméo)
- Task 4.5 – Reaching out to the other technical platforms within EURATOM, e.g. SNE-TP & IDG-TP (lead SCK-CEN, Frank Hardeman)



Multidisciplinary European Low Dose Initiative

Selecting MELODI Priorities for low-dose risk research

MELODI Priorities Ranking: Procedure

- From the latest version of the MELODI SRA, a MELODI statement listing the 10 highest priorities was prepared and approved by the MELODI Bureau. Together, these 10 priorities reflect the scope of the SRA, in a concise formulation
- The list was sent to the 22 MELODI members (as of 1 September 2013) for comments. In addition, MELODI members were invited to select 3 most relevant priorities among the 10 identified in the MELODI SRA. 20 votes were received
- The participants in the 5th MELODI workshop (Brussels, 8-10 October 2013) were also invited to give their opinion by ranking the priorities from 1 (highest relevance) to 10 (lowest relevance). 105 votes were received
- To calculate the total score of each priority, priorities ranked n° 1 received 10 points, priorities ranked n° 2 received 9 points, etc.
- Selected priorities not explicitly ranked were considered equally as n° 1
- The priorities were ranked on the basis of the total score calculated

MELODI Priorities (1)

A. Mechanistic studies

A.1. Characterization of spatial and temporal energy deposition events (track structure and dose rate) and their role in low-dose radiation responses (among others, examination of radiation damage and biological effectiveness (RBE) values of different types of radiation)

A.2. Analysis of mechanisms involved in low dose radiation through use and development of suitable cellular models (2D, 3D, including somatic cells, stem cells, and organo-typic tissue models) as well as animal models

A.3. Identification of specific metabolic pathways and tissue biomarkers (e.g., epigenetic profiles) related to radiation specific tissue responses

A.4. Role of genetic background, immunological status, age, gender and lifestyle on radiation-induced effects, as well as identification of other factors influencing individual radiosensitivity

MELODI Priorities (2)

A. Mechanistic studies (continued)

A.5. Relationships between radio- and chemical toxicity and their respective influence on radiation-induced effects resulting from incorporation (internal contamination) of radionuclides

A.6. Examination of the mechanisms and effects of mixed (radiation/chemical) and multi-exposure (radiation/radiation) on cells, tissues, animal models and humans

A.7. Examination of possible regenerative processes allowing the promotion of medical countermeasures for the treatment of adverse radiological effects (including the effects resulting from the use of radiation in medical applications)

MELODI Priorities (3)

B. Health risk evaluation studies

B.1. Identification, development and validation of biomarkers for radiation-induced health (cancer and non-cancer) effects through sound (molecular, i.e. using most recent methods such as omics, genetic and epigenetic profiling, new generation sequencing and systems biology) epidemiological studies in children and/or adults in conjunction with most suitable and promising retrospective (Techa River, Mayak, Chernobyl, Fukushima, Uranium miners, nuclear workers, secondary cancer patients with radiation therapy in childhood) and prospective (CT scan patients, medical diagnosis patients, new treatment modality RT patients) cohorts with access to biological samples and sound dosimetry

B.2. Development of mathematical and molecular modeling studies based on findings of mechanistic and epidemiological studies dedicated to low-dose health (cancer and non-cancer) risk evaluation

MELODI Priorities (4)

C. Other activities contributing to low-dose risk research

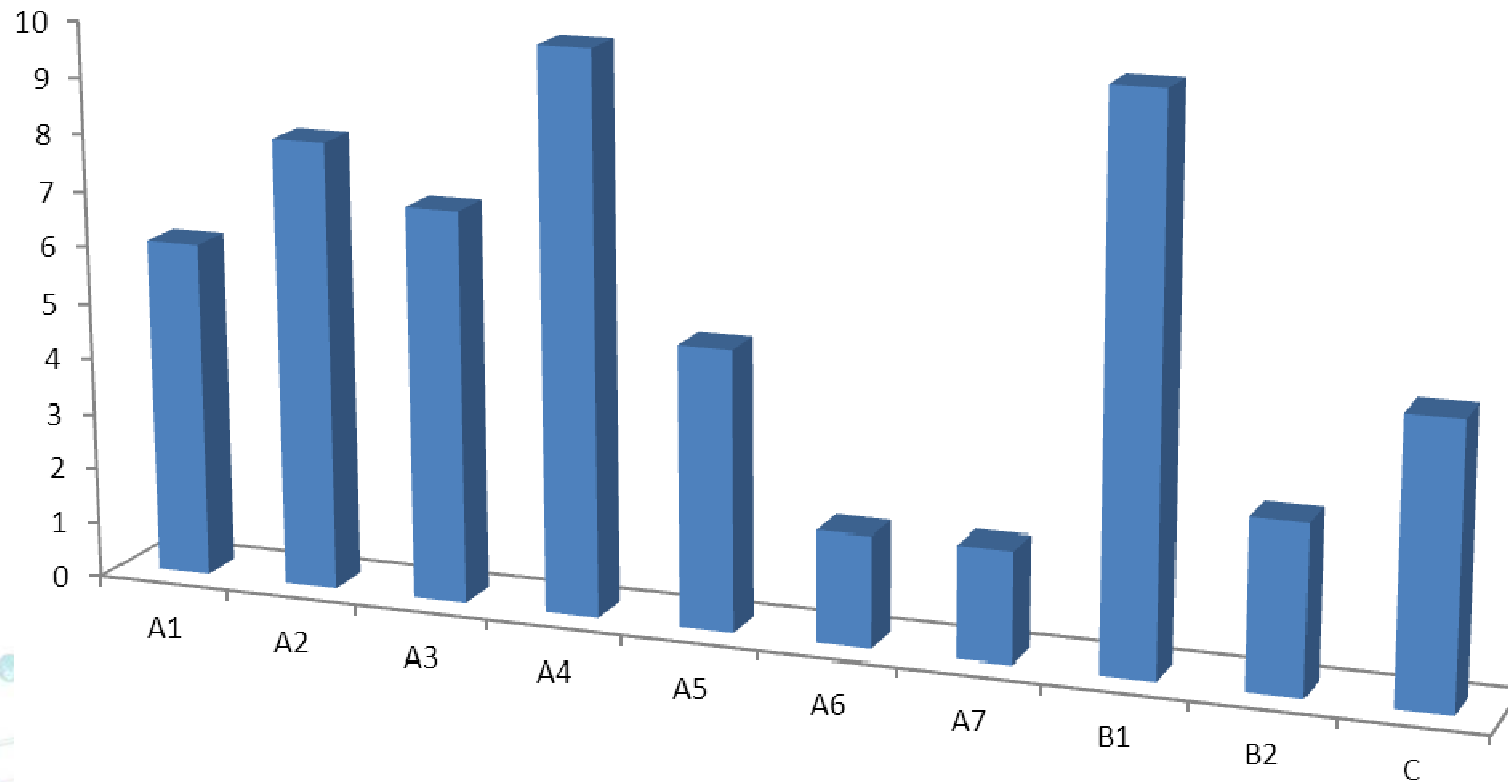
Development and facilitation of access to infrastructures dedicated to low-dose risk research

Consolidation of major cohorts suitable for molecular epidemiological studies

Maintaining a high level of education and training for radiation protection



MELODI Members Priority Ranking (20 votes)



MELODI Members Priority Ranking (20 votes)

1

B.1. Identification, development and validation of biomarkers for radiation-induced health (cancer and non-cancer) effects through sound (molecular, i.e. using most recent methods such as omics, genetic and epigenetic profiling, new generation sequencing and systems biology) epidemiological studies in children and/or adults in conjunction with most suitable and promising retrospective (Techa River, Mayak, Chernobyl, Fukushima, Uranium miners, nuclear workers, secondary cancer patients with radiation therapy in childhood) and prospective (CT scan patients, medical diagnosis patients, new treatment modality RT patients) cohorts with access to biological samples and sound dosimetry

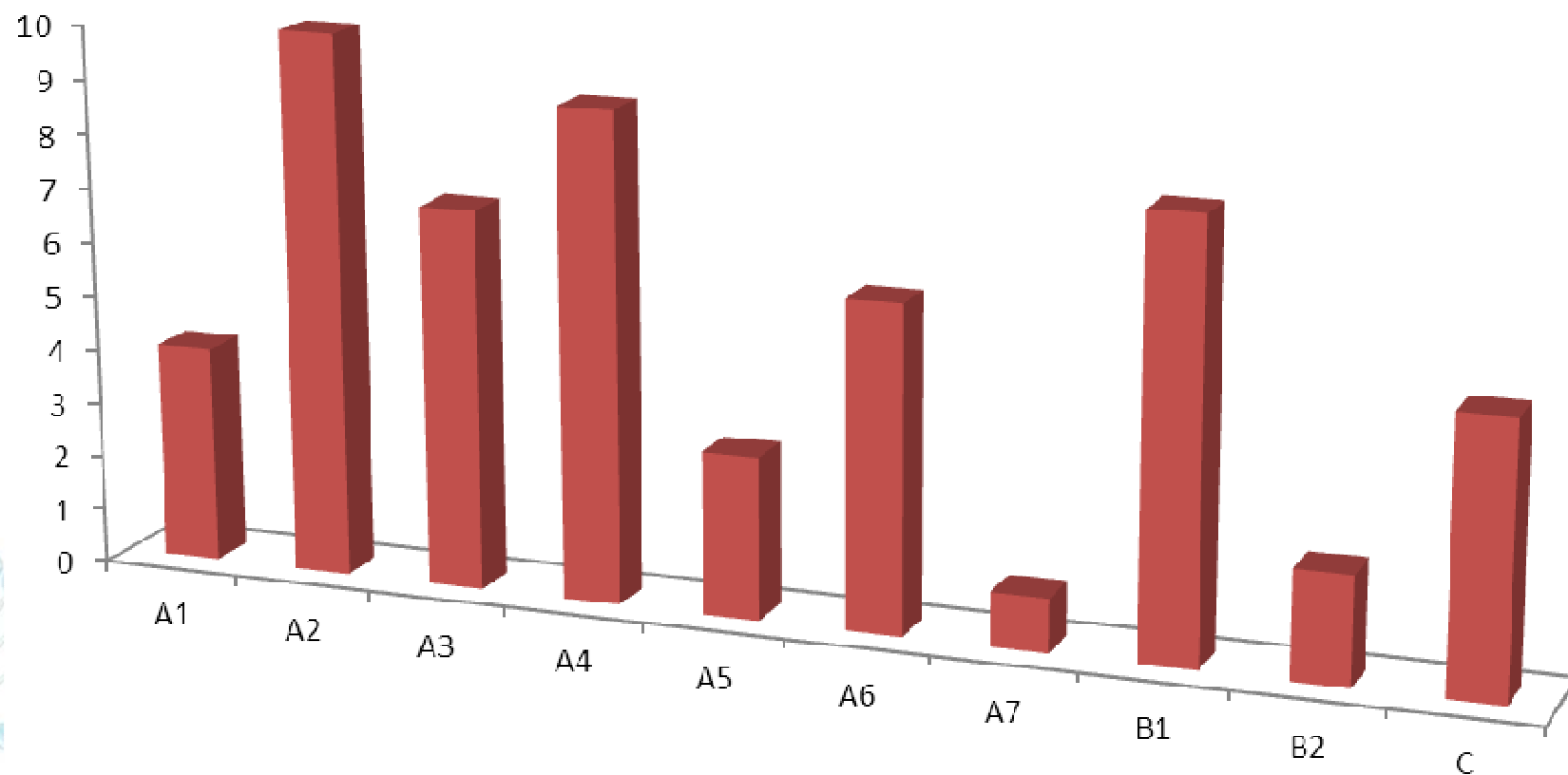
1

A.4. Role of genetic background, immunological status, age, gender and lifestyle on radiation-induced effects, as well as identification of other factors influencing individual radiosensitivity

3

A.2. Analysis of mechanisms involved in low dose radiation through use and development of suitable cellular models (2D, 3D, including somatic cells, stem cells, and organo-typic tissue models) as well as animal models

MELODI Workshop Participants Priority Ranking (105 opinions)



MELODI Workshop Participants Priority Ranking (105 opinions)

1

A.2. Analysis of mechanisms involved in low dose radiation through use and development of suitable cellular models (2D, 3D, including somatic cells, stem cells, and organo-typic tissue models) as well as animal models

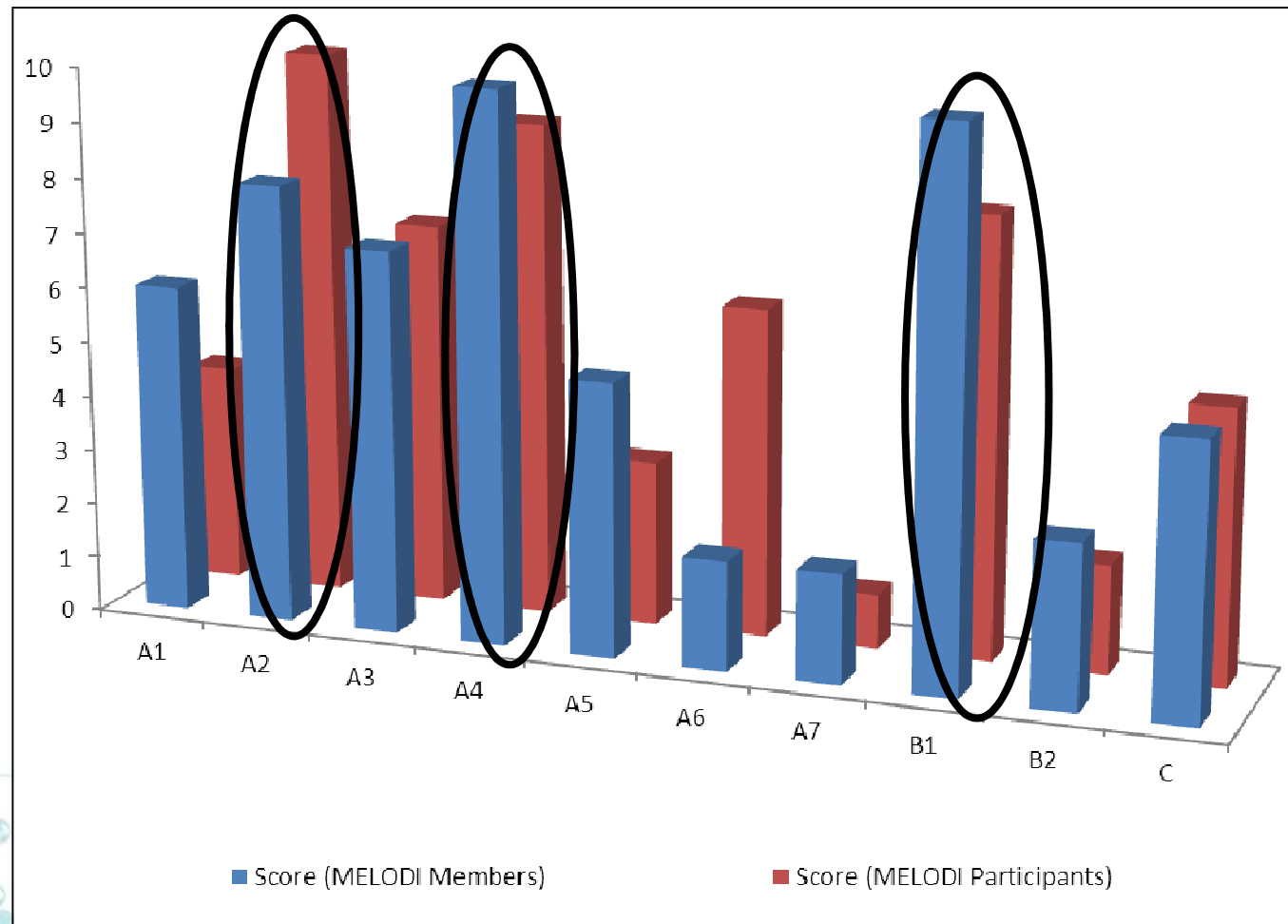
2

A.4. Role of genetic background, immunological status, age, gender and lifestyle on radiation-induced effects, as well as identification of other factors influencing individual radiosensitivity

3

B.1. Identification, development and validation of biomarkers for radiation-induced health (cancer and non-cancer) effects through sound (molecular, i.e. using most recent methods such as omics, genetic and epigenetic profiling, new generation sequencing and systems biology) epidemiological studies in children and/or adults in conjunction with most suitable and promising retrospective (Techa River, Mayak, Chernobyl, Fukushima, Uranium miners, nuclear workers, secondary cancer patients with radiation therapy in childhood) and prospective (CT scan patients, medical diagnosis patients, new treatment modality RT patients) cohorts with access to biological samples and sound dosimetry

Three topics areas A2, A4, B1 emerge as top level priority for a majority of the MELODI community



Next steps (1)

- The content of the next OPERRA call has been specified and the proposals will be evaluated by an independent group of experts. The group of experts consist of 9 members selected from the EU list of experts. The European Commission has select 3 experts and 1 senior expert to lead the group, HERCA 3 experts, UNSCEAR 1 and ICRP 1, respectively
- To ensure the confidentiality of the process, the members of the group of experts are not known to OPERRA & MELODI partners and no direct communication will be made between OPERRA & MELODI and the independent group of experts
- Documents and information have be forwarded to the group of experts and vice versa through an independent go-between operator (GAO) having no conflict of interests with the radiation protection community (cabinet Lallemand & Legros in Brussels). The GAO is also in charge of the organisation of the independent expert group meetings bringing together the experts and representatives of the European Commission

Next steps (2)

- Together with the latest version of the SRA, the independent group of experts in charge of drafting the first OPERRA and COMET (for radioecology) call specifications has been provided with the results of the priority ranking work. This material should be seen as a contribution to the experts' work. It doesn't predetermine their decision nor does it necessarily reflect the content of the future call
- The MELODI Scientific Committee has carefully reviewed the MELODI radiation protection research priorities and provided a comprehensive review statement on these priorities and the priority ranking reflecting their relative feasibility from a scientific point of view. This statement has been also forwarded to the independent group of experts, too
- The first OPERRA and COMET competitive calls and associated documentation have been published on 16 December 2013

http://www.melodi-online.eu/operra_comet_calls.html



OPERRA First Call Topics

- Analysis of mechanisms involved in low dose radiation through use and development of suitable cellular models (2D, 3D, including somatic cells, stem cells, and organo-typic tissue models) as well as animal models
- Determination of the role of genetic background, immunological status, age, gender and lifestyle on radiation-induced effects, as well as identification of other factors influencing individual radiosensitivity
- Identification, development and validation of biomarkers for radiation-induced health (cancer and non-cancer) effects through sound molecular epidemiological studies in children and/or adults in conjunction with most suitable and promising retrospective and prospective cohorts with access to biological samples and sound dosimetry

MELODI Workshop Participants Priority Ranking

1

A.2. Analysis of mechanisms involved in low dose radiation through use and development of suitable cellular models (2D, 3D, including somatic cells, stem cells, and organo-typic tissue models) as well as animal models

2

A.4. Role of genetic background, immunological status, age, gender and lifestyle on radiation-induced effects, as well as identification of other factors influencing individual radiosensitivity

3

B.1. Identification, development and validation of biomarkers for radiation-induced health (cancer and non-cancer) effects through sound (molecular, i.e. using most recent methods such as omics, genetic and epigenetic profiling, new generation sequencing and systems biology) epidemiological studies in children and/or adults in conjunction with most suitable and promising retrospective (Techa River, Mayak, Chernobyl, Fukushima, Uranium miners, nuclear workers, secondary cancer patients with radiation therapy in childhood) and prospective (CT scan patients, medical diagnosis patients, new treatment modality RT patients) cohorts with access to biological samples and sound dosimetry



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