Project title: Implications of Medical Low Dose Radiation Exposure

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Deliverable D6.1

First Stakeholder Board Annual Report

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Table of contents

Abbreviations

SHB: MEDIRAD Stakeholder Board

SF: MEDIRAD Stakeholder Forum

1. Introduction

MEDIRAD WP6 aims to transfer to a wider community (researchers, practitioners, authorities, stakeholders) the operational results reached by the MEDIRAD project, by seeking consensus on proposed recommendations, lessons learnt and solutions. It relies on the extensive networks of the European medical associations and of the MELODI and EURADOS associations, which are brought together into the so-called MEDIRAD stakeholder board (SHB).

According to the MEDIRAD Grant Agreement, the SHB will (i) support the coordination of the MEDIRAD stakeholder related activities, (ii) formulate proposals on the composition of the stakeholder forum (SF), (iii) advise on the design and content of the web-based stakeholder consultation, (iv) contribute in an advisory role to the development of the MEDIRAD recommendations, (v) give views and thoughts on the most suitable ways to ensuring appropriate promotion and dissemination of the MEDIRAD outcomes to concerned stakeholders.

The first year of the MEDIRAD project (1 June 2017-31 May 2018) was devoted to the identification of the MEDIRAD stakeholder board members and of its chair, to the drafting of its terms of reference and the organization of its first annual meeting.

The members of MEDIRAD SHB, who were appointed in line with the provisions of the MEDIRAD Grant Agreement, met for the first time on 13 April 2018 in Rome, Italy, in the context of the second MEDIRAD consortium meeting and General Assembly. They discussed and approved the draft terms of reference, and considered the way forward to implement its mission as an advisory board to the MEDIRAD consortium, interfacing with its respective WP members, and with the stakeholder world outside the consortium. A consensus was reached on the best way to conduct this mission among present SHB members, in the presence of MEDIRAD coordinators, WP leaders and WP6 task leaders.

This report summarizes the appointment process of SHB members and presents the SHB Terms of reference, as well as the approach to be followed in the future as well as its rationale.

2. Content

2.1 Identification of MEDIRAD stakeholder board members and of its chair

During the second half of 2016, the MEDIRAD project coordination team sent a letter (an example is presented in Annex 1) accompanied by a document summarizing the project objectives (Annex 2) to the chairpersons of the following organizations, inviting them to appoint a representative to the MEDIRAD stakeholder board:

- European radiation protection research associations:
  - MELODI (Multidisciplinary European Low Dose Initiative)
  - EURADOS (European Radiation Dosimetry Group)
- European medical societies:
  - 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)
- Other European/international bodies:
  - EPF (European Patients Forum)
  - WHO (World Health Organization)
  - ICRP (International Commission on Radiological Protection)
  - HERCA (Heads of the European Radiological protection Competent Authorities)

On the basis of positive responses received, the following representatives have been appointed as members of the MEDIRAD stakeholder board:

- MELODI: Prof. Sisko Salomaa
- EURADOS: Dr. Zeljka Knesevic
- ESR: Prof. Reinhard Loose
- ESTRO: Prof. Wolfgang Doerr
- EANM: Prof. Gerhard Glatting
- EFRS: Dr. Anders Widmark
- EFOMP: Dr. Virginia Tsapaki
- EPF: Ms. Victoria Fonsou
- WHO: Dr. Maria Perez (special advisor)[1]

In addition, after the official creation of EURAMED (European Alliance for Medical Radiation Protection Research), Prof Christoph Hoeschen was invited to join the group as a representative of this organization.
With regard to the stakeholder board chairperson, it was foreseen in the document "MEDIRAD description of action (DoA)" to appoint Jacques Repussard as independent expert acting as a subcontractor of the IRSN (organization leading the MEDIRAD WP6).
However, in order to comply with the French public procurement procedures, IRSN decided to launch in December 2017 an open call for tenders to give the possibility to other experts interested in

[1] At the time of writing this report, the WHO formal approval procedure has not yet been completed. It is understood that the WHO representative will participate as a "special advisor", thus reserving WHO's neutrality towards any decisions or conclusions formally reached by SHB

chairing the MEDIRAD SHB to submit their proposal. Following this call for tenders, to which only Jacques Repussard responded, his appointment as chair of the SHB was confirmed in January 2018. The composition of the MEDIRAD SHB at the time of writing this report is presented in Annex 3.

2.2 Drafting of the terms of reference for the MEDIRAD stakeholder interface structure

In accordance with the MEDIRAD DoA, the achievement of the milestone MS9 has to be verified by the publication of the list of SHB members as well as of its terms of reference (ToR). To this end, the SHB chair and WP6 leader drafted a first version of the MEDIRAD SHB/SF and sent it to the MEDIRAD coordinators for review on 19 February 2018.

After taking into account some comments and suggestions by the MEDIRAD coordinators, an amended draft was circulated in March 2018 to SHB members, WP leaders and WP6 task leaders in advance of the first SHB meeting held on 13 April 2018 in Rome, Italy. A number of comments were discussed in depth at the meeting, which led to editing of the draft document on several points.

The improvements mainly aimed to:

- Emphasise the consultative role of SHB, the responsibility for production of MEDIRAD results resting solely with the Consortium partners. It was nevertheless understood and agreed that SHB was going to play a proactive role throughout the "MEDIRAD recommendations" production process, and not just at the end of it.
- Clarify the description of the SHB work process and interface with the communities of stakeholders, through the SF in particular.
- Clarify the ethical rules which SHB and SF members should observe in the course of their actions with respect to the MEDIRAD project. In particular, the following two important principles were agreed:
    - SHB/SF are advisory bodies of MEDIRAD, where members act on behalf of the institutions which nominated them, but do not have a mandate to formally endorse MEDIRAD results. The stakeholder consultation process (SHB and SF) will make an input into MEDIRAD results, particularly the four Recommendations which will be elaborated by WP6, however the institutions which are represented in this consultation process cannot be considered as having formally endorsed or approved their contents. This important consideration will be recalled in a text which will be included, in a disclaimer section, in each of the future recommendations.
    - It will be paramount to ensure that potential conflicts of interest within the stakeholder consultative process do not alter the quality and credibility of the MEDIRAD recommendations. Towards this objective, SHB members have advised that SF nomination process should address relevant collective (pan European or national) organisations rather than individual persons or corporations to which they belong. SHB/SF members will also be expected to formally disclose their respective interests with respect to the MEDIRAD problematics.

As a result of a final consultation of SHB members, the updated version of the ToR of the MEDIRAD stakeholder interface structure (presented in Annex 4) has been approved by the MEDIRAD SHB members on 11 May 2018 and published on the MEDIRAD project website.

2.3 Organization of the first MEDIRAD stakeholder board meeting

The first meeting of the MEDIRAD stakeholder board has been held on 13 April 2018 in the premises of the Sapienza University in Rome, Italy. The meeting followed the agenda provided in Annex 5. The minutes of the meeting, as approved by the participating SHB members, are provided in Annex 6.

Seven of the eleven SHB members, including its chair, attended the meeting (Jacques Repussard, Sisko Salomaa, Željka Knežević, Viktoria Fonsou, Maria del Rosario Perez, Reinhard Loose, Christoph Hoeschen) and apologies were received from the three other SHB members (Virginia Tsapaki, Anders Widmark, Gerhard Glatting, Wolfgang Doerr), who could not come to Rome due to prior engagements, the meeting having unfortunately been confirmed at a rather late stage.

The MEDIRAD coordinators and the EIBIR MEDIRAD administration team were present, as well as leaders of MEDIRAD WP2, 3, 5, 6, and WP6 task leaders.

2.3.1 MEDIRAD overview

The first part of the meeting was dedicated to an overview of the MEDIRAD project goals and general organisation, with an emphasis on WP6 where task leaders presented their respective role. SHB members had also been invited to attend as observers all sessions and dinner of the MEDIRAD consortium annual meeting, which took place before the SHB meeting, so as to become better acquainted with the project and its actors.

2.3.2 Terms of reference for the MEDIRAD stakeholder interface structure

The second part of the meeting was devoted to the finalization of the MEDIRAD stakeholder interface structure ToR. The outcome of the discussion is presented in section 2.2 of this report.

2.3.3 Planning of the stakeholder related tasks

2.3.3.1 Constitution and operation of the stakeholder forum

MEDIRAD stakeholder forum (SF) membership (max 150 persons) is expected to gather representation by stakeholder organisations of interest for the action field of MEDIRAD:

- Medical and radiological sciences (researchers and practitioners)
- Patients
- Healthcare worker organisations
- Regulatory organisations
- Radiological equipment industry

SHB recommended that MEDIRAD (WP1 in consultation with WP6) prepared a list of pertinent European and national organisations, and a standard letter to invite them to nominate a representative in the MEDIRAD SF. SHB should be consulted on the draft list and letter.

As it can be anticipated that the draft recommendations which SF will be consulted on will not be ready until the later part of the MEDIRAD project, SHB recommended that an interface with SF should be initiated soon after its constitution, in order to make SF members well aware of MEDIRAD context and objectives, and ready to interface in a meaningful way, including within their respective organisations. Thus a first questionnaire will be elaborated by WP6, in consultation with SHB, to initiate this interface with SF. All communication with SF will be operated through the dedicated internet based tool set up by WP6, which provides confidentiality as well as an effective recording and electronic dialogue system.

2.3.3.2Interfacing with the production of MEDIRAD recommendations

A key objective of WP6 is to formulate to decision-makers and practitioners science-based policy recommendations for the effective protection of patients and medical workers and the general public, with the support of a web-based consultation of a wide range of stakeholders, in the four following areas:

- To promote standardized procedures to facilitate the development of Europe-wide data repositories of patient exposure to IR (dosimetric information, imaging records) for the purpose of optimizing medical protocols and facilitating further research on low-dose effects.
- To contribute to an optimized medical use of IR by disseminating relevant information based on MEDIRAD results among clinicians, radiologists, radiographers, nuclear medicine physicians and medical physicists.
- To help enhance the robustness of the European RP system, in the context of the implementation of Council Directive 2013/59/Euratom (the revised European BSS Directive).
- To disseminate relevant information about MEDIRAD results to the concerned scientific communities both in the medical and nuclear sectors, in order to further bring together these communities, as well as to competent authorities, and contribute to the continuous elaboration and updating of strategic research agendas (SRAs) and associated roadmaps relevant to RP research in Europe.

Acting in a consultative manner, SHB/SF will act as go-between for the MEDIRAD researchers and their stakeholders in society in order to help elaborating purposeful recommendation contents. As the MEDIRAD project research unfolds, its final results are obviously not yet known, but the objectives and modes of scientific investigation are. This information should be in a first stage conveyed to stakeholders in SHB/SF, together with information on the goals of the future recommendations. With the support of a short questionnaire, this exchange with SHB/SF should provide valuable feedback on the expectations of the stakeholder communities, which will in turn help the recommendation drafting process. Thus, in a complementary approach to scientific publications which constitute the formal detailed record of research results at the end of a project, the MEDIRAD recommendations aim to offer science end users some MEDIRAD research-based evidence in support to the generic goal of optimising and enhancing radiation protection behaviour with respect to medical applications of ionising radiation. This means that the recommendation drafting process can be engaged in parallel to the research itself, feeding on its investigations and results as they gradually occur, as well as on a gradually better understanding of stakeholders actual concerns and expectations. In a first stage, a generic text about the nature and the production process of the recommendations could be elaborated by WP6 in consultation with SHB, together with a first draft architecture for the contents of each recommendation, for the purpose of engaging the dialogue at SF level.

2.3.4 Next steps

2.3.4.1Constitution of the stakeholder forum

SHB members recommended that MEDIRAD invites:

- The organisations represented in SHB,
- The MEDIRAD research partners,

to propose names of institutions, at European and national levels, to be contacted towards the formation of SF. On the basis of this information, WP6/WP1 in consultation with SHB will elaborate a balanced SF composition draft (balanced in terms of representation of countries and of sector

interests). Once this draft structure approved in principle, WP1 will contact the entities to invite nomination of a representative in SF. The goal is to include no more than 150 participants in the MEDIRAD stakeholder forum.

SHB noted that the internet based structure to support SF operations is already operational thanks to the task 6.2 leader SCK•CEN.

2.3.4.2First questionnaire towards SF members

Once the SF membership is established, communication with MEDIRAD should be initiated without delay. For this purpose, a first working document about the recommendations elaboration foreseen process, together with general information about MEDIRAD and a short questionnaire on stakeholder expectations, will be sent to SF members. Guidance on MEDIRAD ethics and on how SF members can interact with their own constituent organisations or members on MEDIRAD problematics will also be distributed.

2.3.4.3Planning for next meetings of SHB

SHB recommended that its next meeting, in the context of the MEDIRAD consortium annual meeting, should be placed in the agenda in such a way as to allow sufficient time to manage its agenda, and interface with MEDIRAD WP's. In practice, this probably means that a whole day should be made available (one half day for SHB itself, with MEDIRAD coordinators/WP6/WP1 task leaders in support, and one half day to exchange with WP2/3/4/5).

In addition, it was noted that some further SHB exchange in teleconference mode would most probably be needed before the above meeting.

3. Conclusion

The first SHB meeting, held in Rome, on 13 April 2018 with the participation of most MEDIRAD WP leaders and relevant task leaders (in WP6) was a key event for the establishment of this MEDIRAD Deliverable 6.1 in the sense that it allowed to build a good consensus on the role of SHB, on the best way to approach MEDIRAD stakeholder dialogue issues, and to identify the next action steps.

4. Annexes

4.1 Annex 1: Letter of invitation to nominate a representative in the MEDIRAD SHB

Dr. Emilie van Deventer
WHO Team Leader of the Radiation Program
vandeventere@who.int
cc: perezm@who.int

Vienna, 7 September 2016

Subject: Information on MEDIRAD Project under Horizon 2020 NFRP-9 Call & Invitation to join Stakeholder Board

Dear Dr. van Deventer,

We are contacting you as the coordinating team of a consortium that is preparing a project submission for the H2020 EURATOM Call NFRP-9 (Impacts of low dose radiation exposure). The project is entitled "Implications of Medical Low Dose Radiation Exposure" (acronym MEDIRAD)

We would like to invite the WHO to designate a representative to the **Stakeholder Board** of the project. This board will have an advisory role and act as multiplier in particular for dissemination activities of the project findings and recommendation documents.

Next to developing novel science in radiation protection, in which leading experts from the various disciplines will be involved, the project also aims to transfer to a wider community (research, practitioners, patients, authorities, other stakeholders) the operational results reached by the MEDIRAD project, by seeking consensus on proposed recommendations, lessons learnt and solutions.

I attach a brief confidential outline of the project for your information.

One of the key tasks of the Stakeholder Board will be to support populating the larger electronic Stakeholder Forum that will be consulted on the science-based policy recommendations that the project will develop with the aim to build consensus on these documents. The Stakeholder Board will meet five times during the 4-year project. Due to the limited project funds, your organisation's contribution would need to be cost-neutral to the project.

The engagement with the stakeholders will be within the competence of work package 6 led by the French Institute for Radiological Protection and Nuclear Safety (IRSN), which will be in touch to discuss details if and when the project has been positively evaluated by the European Commission.

We look forward to hearing from you and very much hope that WHO will agree to join the project's Stakeholder Board if awarded. Please do not hesitate to let us know if you require further information related to the project at this stage in order to be able to take a decision on above requests. If possible we would appreciate an answer by September 16.

With kind regards,

Prof. Guy Frija
MEDIRAD Clinical Coordinator

Prof. Elisabeth Cardis
MEDIRAD Scientific Coordinator

4.2 Annex 2: Overview of the MEDIRAD project

MEDIRAD PROJECT

Implications of Medical Low Dose Radiation Exposure

General overview document

28 July 2016

Following the resignation of Dr. Peter Jacob from the MELORAD leadership, extensive discussions have taken place, mainly between the medical associations, to resolve the pending issues which were analysed as primarily caused by the complexity of the project concept, and by the diversity of its ambitions.

A new project called MEDIRAD has emerged, which is briefly presented below. Most scientific partners who had taken interest in MELORAD and participated in the earlier preparatory work will have an opportunity to take part in MEDIRAD.

This project aims to respond fully to the EURATOM call NFRP-9 and is built on 3 pillars. It is coordinated jointly by Elisabeth Cardis (ISGlobal) and Guy Frija (Université Paris Descartes).

The first one is dedicated to a better understanding of low-dose effects, using mechanistic studies based on radiobiology and on clinical cohorts. The improved understanding of the development of late health effects after exposure to low-dose radiation exposure will be integrated into mechanistic models that will be used to re-analyse existing epidemiological data and to improve radiation risk assessments. The second pillar is aimed at building the relevant tools that are currently lacking, focused on dosimetry optimisation, image quality, image biobanking, and dose exposure repositories. The third one is devoted to establish recommendations to the European Commission and to Member States for regulatory purposes, and also for supporting future research projects and for the dissemination of innovative tools.

The project will address a wide range of low-dose patient medical exposure situations, in order to further develop dosimetric and risk models and draw operational recommendations for improving radiation protection.

Taking into account the available budget, it is proposed to focus the project on the exploration of radiation-induced risks associated with medical irradiation protocols representative of situations commonly occurring in the European health systems. Consistently with the overarching questions arising from radiation protection issues, it is also necessary to study endpoints related to both cancer and non-cancer risks. As the occurrence of cardiac diseases is one of the most important affecting European citizens, and as medical procedures involving ionizing radiation of the chest area are performed for a significant number of patients, it is envisaged to address in MEDIRAD health risks related to these procedures. In the field of cancer, because CT scanning represents a major contribution to population doses from medical sources and because of radiation protection concerns about paediatric exposures, MEDIRAD will in particular focus on the estimation of cancer risk following paediatric CT scanning and the identification of factors (host and environmental) that may modify this risk.

Finally, an important aim of the project is to undertake a unified approach of the concept of low-dose risks by developing a risk model based on a large range of dose exposure values, and by using high quality data provided by the establishment of relevant tools for collection, storage and analysis. To achieve this task, we will use different clinical cohorts, different exposure modalities (diagnostic and therapeutic), and innovative imaging and circulating biomarkers.

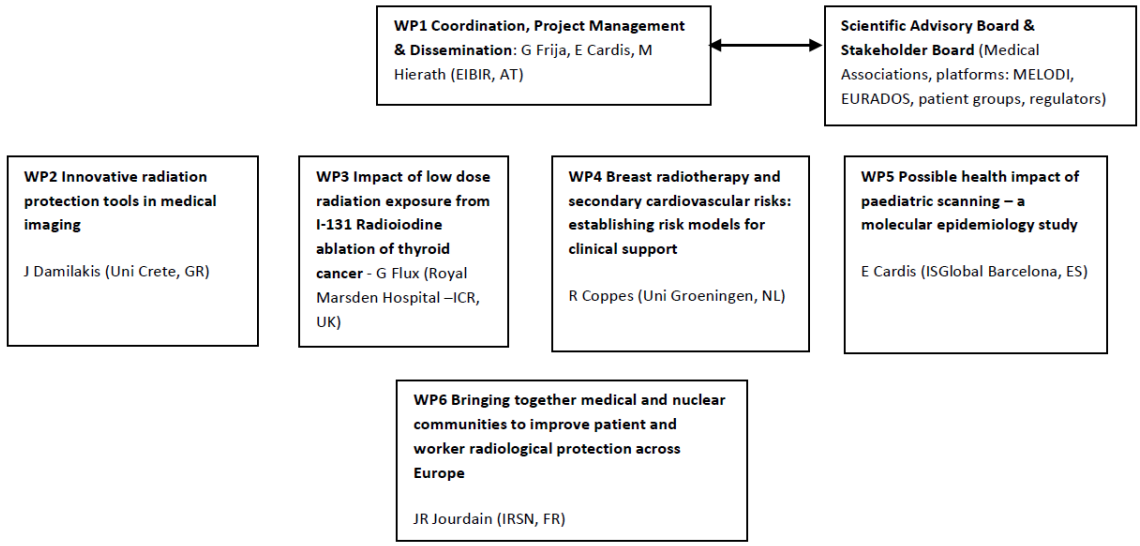
Given the high complexity of the problem being addressed, it will be essential for the project's success to ensure from the start the pertinence and the quality of the patient data to be collected and analysed, and to rely on strong mechanistic experimental radiobiology and molecular epidemiology approaches. Considering also the need to ensure a sufficient statistical validity of the proposed risk models, it will be appropriate to organise the project around 2 key concepts, aiming at the evaluation of respectively biomarkers of individual sensitivity (concept 1), and of biomarkers of cardiovascular changes, combined where necessary to imaging biomarkers of cardiovascular changes following a medical irradiation protocol (concept 2). The chosen irradiation protocols must also be representative of today's medical practice and related technologies, studying in particular the higher end of the "low-dose" range in order to address effectively any needs for practice improvements. In declining order of the magnitude of the doses to organs, cohorts for the following exposure conditions will be studied: radiation therapy of breast cancer, ablation of thyroid cancer with radioactive iodine, and computed tomography in the chest region.

- **Patients with radiotherapy for breast cancer**: This protocol leads to high to moderate dose exposures to the heart region, and to moderate to low-dose exposures of other parts of the body, thus placing these patients as eligible for both cohort concepts.
- **Patients undergoing ablation of thyroid cancer with radioactive iodine**: These protocols belong to the moderate to low-dose exposures. Related patients could belong to both cohort concepts.
- **Patients undergoing CTs**: These protocols belong to the low-dose range. Related patients could belong to concept 1.

Appropriate and innovative molecular and imaging patient data will be used, and feed into the risk modelling, with the objective to link dosimetric data to early and late observed molecular effects in the blood and mechanistic effects in the heart on the one hand, and the related radio-induced pathology risk on the other hand.

Six work packages have been established for this project.

Simplified MEDIRAD Work Package Structure



Work Package Description

WP2 addresses the part of the call related to the need to establish imaging-health related structures in relation with dose exposure which would be relevant for the achievement of the current project and for future research projects.

WPs 3, 4 and 5 address radiological risks to healthy tissues and organs exposed during currently practiced medical irradiation protocols (nuclear medicine, radiotherapy, CT). Each WP addresses the clinical aspects of the research (patient cohorts, dosimetry and observation/measurement of suitable biomarkers), the mechanistic aspects of low-dose irradiation (if applicable), and the modelling of risk.

WP5 includes a molecular case-control of leukaemia nested within large scale cohorts of paediatric CT scan patients to a) derive sound scientific information about the magnitude of CT radiation risk as input to optimisation and b) identify potential genetic or epigenetic factors which may confer an increased risk of radiation induced cancer with a view to identifying patients who may benefit from alternative diagnostic techniques.

Overall coordination of working methods, and interactions with WP2 where appropriate are managed under the authority of the coordinators in consultation with the Scientific Advisory Board.

WP6 aims to transfer to a wider community (researchers, practitioners, authorities, stakeholders) the operational results reached by the MEDIRAD project, by seeking consensus on proposed recommendations, lessons learnt and solutions. It relies on the extensive networks of the European medical associations and of the MELODI and EURADOS platforms.

4.3 Annex 3: Composition of the MEDIRAD stakeholder board

4.4 Annex 4: Approved terms of reference for the MEDIRAD stakeholder interface structure

Terms of reference for the MEDIRAD stakeholder interface structure

Final Version – 14 May 2018

Introduction to the Euratom MEDIRAD project

Background

In today's Europe, the population's exposure to ionising radiation[2] (IR) is overwhelmingly due to the implementation of medical protocols either for diagnostic or therapy purposes. This exposure tends to increase over time, as the use of such protocols is being developed with the wider availability of advanced technologies. The rationale for each patients' exposure is based on the foreseen medical benefit over the risk induced by the radiation dose associated to a given protocol. Each individual medical decision is guided by the existing knowledge on a) the expected results from the protocol (for example: high quality imaging based diagnostic, or cancer treatment benefit, in relation to the dose administered), and b) the health risks induced by the exposure (long term possible consequences of cumulated radiation exposure, or pathological effects on healthy tissue close to the irradiated tumour). This radiation protection knowledge is derived from research, and is codified in professional and regulatory guidance and formal international publications such as those of the ICRP, where scientific consensus is sufficient. However, as medical exposure of the population increases, a number of significant remaining gaps in this knowledge have been identified, which ongoing research aims to fill, in particular through the Euratom research program, which funds the MEDIRAD project.

Objectives of MEDIRAD

The Euratom scientific community has come to the conclusion, for the area of radiation protection research, that only an active policy aiming to integrate research across Europe, bringing together national programs, as well as the relevant disciplinary fields would have the potential to overcome the complexities of some of the open scientific questions of interest to optimise radiation protection. In the

[2] ICRP distinguishes three kinds of exposure to ionising radiation: "**existing exposures**" which result from natural sources (or residual sources of radiation following radioactive pollution), "**planned exposures**", which result from deliberate actions, concerning workers in their professional environment, or patients undergoing medical protocols, and "**emergency situation exposures**" which may occur in the context of radiological accidents. Specific recommendations are published and regularly updated by the ICRP, on the basis of research results, to provide guidance for the optimisation of protection of people and the environment against the risks induced by such exposures. In the case of patients, optimisation is chiefly a responsibility of the medical professionals involved who need to assess the risk/benefit balance of the envisaged ionising radiation exposure in light of existing regulations, good practice and scientific findings.

specific field of medical uses of ionising radiation, this policy brings together medical and nuclear scientific communities in order to improve patient and worker radiological protection across Europe. This is the strategic goal of MEDIRAD, which will be addressed by combining two complementary approaches: a) demonstrating the scientific added value of combining multi-disciplinary and transnational teams from both medical and nuclear (radiation protection) domains, by addressing some selected and well identified research issues of importance; b) demonstrating the potential of stakeholder influence in enhancing the actions aimed at improving radiation protection for patients and also medical professionals, on the basis of new scientific evidence. Such actions may be directed towards research itself, to promote the development of new projects on priority issues; towards the medical professionals, to promote recent research results and facilitate their translation in everyday practice; towards the competent authorities, to promote the integration of research results into regulatory framework under the auspices of European legislation on radiation protection (so called Basic Safety Standards (BSS) Directive[3]).

Work package (WP) structure

MEDIRAD is operated by a consortium of 33 partners from 14 European countries[4]. The foreseen tasks have been regrouped under 6 Work Packages, each having a lead consortium member:

WP1 - Project management and dissemination (EIBIR, European Institute for Biomedical Imaging Research): Work package 1 will take care of the general project management and administration of the MEDIRAD Project. It will liaise with the European Commission (EC), facilitate effective information exchange within the consortium, address contractual and reporting requirements, and coordinate the project governance.

WP2 - Dose evaluation and optimisation in medical imaging (University of Crete): Work package 2 will develop novel methodologies to reduce patient and staff radiation dose and potential radiation-related risks of cancer and non-cancer outcomes from chest imaging, while maintaining or improving diagnostic information from existing and emerging techniques. Work will focus on state-of-the-art CT, fluoroscopically-guided interventional procedures and hybrid systems. Detailed dosimetric data will be produced, which will be valuable for optimising RP of patients from high-dose diagnostic and interventional procedures, as well as for input to epidemiological radiation protection research studies and development of models of radiation-induced risk. An integrated imaging and dose biobank will be developed to address research needs.

[3] Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionizing radiation (official Journal of the EU 17 January 2014). *The English version will be made available as a reference document on the MEDIRAD workspace within the SCK-CEN SharePoint.*

[4] The Grant Agreement is a contract signed between the EC and the Consortium partners to define the objectives, tasks, deliverables, financial conditions and responsibilities of the partners for the execution of the Project. *The MEDIRAD description of work (Annex 1 of the Grant Agreement) will be made available as a reference document on the MEDIRAD workspace within the SCK-CEN SharePoint.*

WP3 - Impact from low-dose radiation exposure from I-131 radioiodine (NaI) ablation of thyroid cancer (Royal Marsden National Health Service Trust): Work package 3 will develop and implement the tools necessary to establish, for the first time in a multicenter setting, the range of absorbed doses delivered to healthy organs undergoing thyroid ablation and the threshold absorbed dose required for a successful thyroid ablation. This will enable patient specific treatment planning that will minimize risk to the patient while ensuring a successful outcome and will facilitate development of a large scale epidemiological study of the effect of low absorbed doses from irradiation of normal organs with internal sources of radionuclides.

WP4 - Breast radiotherapy and secondary cardiovascular risks: establishing risk models for clinical support (University Medical Center Groningen): Work package 4 will integrate clinical epidemiology, radiobiology, and modelling approaches to gain more insight into the mechanisms leading to radiation-induced cardiotoxicity in breast cancer patients and to develop and validate classical Normal Tissue Complication Probability and mechanistic models to relate low to moderate doses to the heart to a variety of biological, subclinical and clinical endpoints. WP4 aims to contribute to more accurate risk estimations for early and late radiation-induced cardiovascular biological and clinical events and thus provide potential targets for primary and secondary prevention.

WP5 - Possible health impact of pediatric scanning – a molecular epidemiology study (Barcelona Institute for Global Health, ISGlobal): Work package 5 will improve the direct estimation of cancer risk following low doses of ionising radiation from CT scanning in childhood and adolescence and to study the role of confounding factors - including age, genetic and epigenetic variants which may modify this risk.

WP6 - Bringing together medical and nuclear scientific communities to improve patient and worker radiological protection across Europe (IRSN, French Institute for Radiological Protection and Nuclear Safety): Work package 6 will formulate to decision-makers and practitioners science-based policy recommendations for the effective protection of patients, medical workers and the general public. WP6 will organize a web-based consultation of a wide range of stakeholders and disseminate the MEDIRAD results to broader communities interested in radiation protection.

Timeline

The project duration is 4 years, from June 2017 to May 2021.

MEDIRAD and its stakeholder community

WP6 Objectives

In line with the title of WP6 *(Bringing together medical and nuclear scientific communities to improve patient and worker radiological protection across Europe),* the objectives are defined as follows in annex 1 of the Grant Agreement:

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

• Develop and promote 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 IR (dosimetric information, imaging records) for the purpose of optimising medical protocols and facilitating further research on low-dose effects.

• On the basis of the findings from WP2, WP3, WP4 and WP5, develop and promote consensus recommendations on optimised medical use of IR and disseminate relevant information among clinicians, radiologists, radiographers, nuclear medicine physicians and medical physicists.

• On the basis of the findings from MEDIRAD WPs and the lessons learned from a web consultation of a wide range of stakeholders, develop and promote consensus recommendations towards enhancing the robustness of the European RP system, 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, in order to further bring together these communities, as well as to competent authorities, and contribute to the continuous elaboration and updating of strategic research agendas (SRAs) and associated roadmaps relevant to RP research in Europe."

WP6 composition and task structure

The six following MEDIRAD consortium partners will be involved in WP6 operations:

- European Institute for Biomedical Imaging Research (EIBIR, AT): Monika Hierath, Ulrike Mayerhofer-Sebera
- Barcelona Institute for Global Health (ISGlobal, ES): Adelaida Sarukhan, Rafael Vilasanjuan, Elisabeth Cardis
- Belgium Nuclear Research Centre (SCK•CEN, BE): Nathalie Impens, Filip Vanhavere

- Institute for Radiological Protection and Nuclear Safety (IRSN, FR): Jean-René Jourdain (WP6 Leader)
- Istituto Superiore di Sanità (ISS, IT): Antonella Rosi, Cinzia De Angelis, Alessandra Palma, Sveva Grande, Sara Della Monaca
- University College Dublin (UCD, IE): Jonathan McNulty, Shane Foley

All communication should be done through the Sharepoint software tool developed for the purpose of MEDIRAD stakeholder activities, for which members of SHB/SHF will receive individual access passwords.

WP6 is responsible for the four following tasks, in line with the defined objectives:

- Task 6.1: Setup and management of Stakeholder Board (SHB) and Forum (SF) *(Lead: IRSN)*
- Task 6.2: Setup and operate the MEDIRAD consensus formation infrastructure *(Lead: SCK•CEN)*
- Task 6.3: Develop recommendations to enhance radiological protection of patients, doctors, medical physicists, and radiographers *(Lead: SCK•CEN)*
- Task 6.4: Promotion and dissemination of MEDIRAD results among relevant stakeholders *(Lead: EIBIR)*

Expected WP6 deliverables

No	Description	Lead	Due date
D6.1	First stakeholder board annual report	IRSN	M12
D6.2	Report on the stakeholder forum: composition, content of the web-consultation, guidelines for the use of the stakeholder infrastructure	SCK•CEN	M12
D6.3	Second stakeholder board annual report	IRSN	M24
D6.4	Third stakeholder board annual report	IRSN	M36
D6.5	MEDIRAD first recommendations (final version)	UCD	M42
D6.6	MEDIRAD second recommendations (final version)	ISS	M42
D6.7	MEDIRAD third recommendations (final version)	SCK•CEN	M42
D6.8	MEDIRAD fourth recommendations (final version)	IRSN	M42
D6.9	Report on the organization and findings of the two seminars organized within Task 6.4	IRSN	M48

Expected WP6 milestones

No	Name	Lead	Due date	Mean of verification
MS9	Stakeholder board established	EIBIR	M6	Publicly available member list and ToRs
MS11	Description of the plan to setup the Stakeholder survey	SCK•CEN	M8	Content of survey finalized
MS21	Stakeholder forum	SCK•CEN	M12	On-line forum operational with publicly available participant list
MS31	Recommendation WGs	SCK•CEN	M24	WGs operational
MS51	Dissemination seminars	IRSN	M42	Detailed agendas of seminars available and list of participants decided

Stakeholder Board (SHB)

Membership

Taking into account the key policy objective expected by EURATOM from the MEDIRAD project, which is to demonstrate and emulate the scientific gains of a close research partnership between the medical and nuclear scientific communities, it is essential to the project's goal to ensure that these wider communities, and their natural stakeholders are enabled to observe this partnership experience, and discuss its results in terms of enhancement of radiation protection in the medical field. For this purpose, a two-tier stakeholder consultation system has been foreseen:

- The relevant European societies and research organisations compose a first tier, the Stakeholder Board (SHB), to interface with the MEDIRAD project and advise on the development of stakeholder consultation process.
- The Stakeholder Forum (SHF), made up of a larger number of representatives, will be responsible for extending the consultation process to all relevant entities at European and national level.

The composition of the Stakeholder Board is as follows, as of end 2017, in accordance with the provisions of the MEDIRAD Grant Agreement (Annex 1):

- Chair: Dr. Jacques Repussard
- EURADOS: Dr. Zeljka Knesevic
- MELODI: Prof. Sisko Salomaa
- ESTRO: Prof. Wolfgang Doerr
- EANM: Prof. Gerhard Glatting
- EFOMP: Dr. Virginia Tsapaki

- EFRS: Dr. Anders Widmark
- ESR: Prof. Reinhard Loose
- EPF: Ms. Victoria Fonsou
- EURAMED: Prof. Christoph Hoeschen
- Special adviser from WHO: Dr. Maria Perez

Mission

As defined by the Grant Agreement, the mission of the SHB is as follows:

- The SHB will support the coordination of the MEDIRAD stakeholder related activities.
- The SHB will formulate proposals on the composition of the stakeholder forum (SF) with the support of the coordinators, and WP6 partners.
- The SHB will advise on the design and content of the web-based stakeholder consultation.
- The SHB will contribute in an advisory role to the development of the MEDIRAD recommendations.
- The SHB will give views and thoughts on the most suitable ways to ensuring appropriate promotion and dissemination of the MEDIRAD outcomes to concerned stakeholders by providing opinions on the agendas and outcomes of the seminars.

Role and responsibilities of SHB members

SHB members are expected to contribute actively, in an advisory function towards the WP6 Consortium partners, to the following tasks:

- Content of the web survey and infrastructure to consult Stakeholder Forum (SF) members on the contents of recommendations that will result from MEDIRAD research.
- Identification of the participants in the web-based SF, which will be the basis for wide ranging consultation on the draft recommendations. This forum should be able to reflect both the different concerned communities (medical professionals, radiation protection experts and authorities, patients, researchers) and the countries of the EU (at least those with research organisations engaged in the MEDIRAD project).
- Development by WP6 of guidance specific to the ethics of stakeholder dialogue and consultations on MEDIRAD related issues, which may be required for reference by MEDIRAD partners, SHB members and SF members. Such guidance would for example address the precautions to be taken when discussing radiation protection issues, concerning patients in particular, on the basis of ongoing scientific research results and underlying hypothesis.
- Overseeing the operation of the SF.

- Interact with the four WP6.3 working groups tasked to draft the recommendations, on the basis of MEDIRAD incoming scientific results and in close consultation with the MEDIRAD WPs in charge of the research tasks. These recommendations will respectively address the following topics:
    - Standardised procedures for patient data repositories.
    - Patients' radiological protection, aiming at medical professionals.
    - Patients and workers radiological protection, aiming at policy makers and competent authorities.
    - Future radiological protection research, aiming at the research community.
- Review of the foreseen recommendations, taking into account the results of the Stakeholder Forum consultation and the positions of the MEDIRAD project partners.
- Provide advice and support towards the preparation of the two seminars (planned at Month 45 of the project, i.e. February 2021) foreseen to contribute to the dissemination of MEDIRAD results and recommendations.

Ethics of stakeholder dialogue

Through the stakeholder dialogue process, members of SHB/SHF will be in the capacity to observe ongoing research activities, and access documents from MEDIRAD, as well as from fellow stakeholders, which are not publicly available. In order to ensure that this consultation process is as a whole ethically acceptable, and may as such contribute to the future publicly available results of MEDIRAD, SHB and SHF members will need to comply with the following three principles:

- **Disclosure of interests**: SHB/SHF members will be invited to disclose to MEDIRAD their professional or otherwise links to third parties possibly interested in MEDIRAD results,
- **Confidentiality:** whenever MEDIRAD documents made available through the stakeholder consultation process are labelled "not publicly available", SHB/SHF members will ensure that such documents are strictly used for the MEDIRAD consultation process, and in particular not published on open websites.
- **Transparency:** SHB/SHF members will ensure that the dialogue on MEDIRAD related issues takes duly into account the whole of the information made available (and not a chosen subset). For example, information about research experimental conditions, and uncertainties accompanying its results, are essential to ensure an ethically acceptable discussion of their possible significance.

Stakeholder Forum (SF)

The SF is a web-based group expected to gather a number of up to 150 participants from the different countries and communities concerned by the MEDIRAD developments and future results. The SF will be mainly consulted through e-surveys that will be based on questions elaborated by WP6 participants in collaboration with the SHB. It will also constitute an important resource for input into the two seminars aiming at the dissemination of MEDIRAD results. SF members will be expected to liaise within their respective community in order to express as far as possible collective views on the issues being discussed.

Supporting infrastructure

Information sharing system

The SHB members will be provided with access rights to a restricted Sharepoint ® based workspace. A folder dedicated and only accessible to the SHB members, the task leaders and partners in T6.1, T6.2 and T6.3 will be setup, where the SHB can collect its documents.

The restricted workspace will also contain folders only accessible to the SF members, the task leaders and partners of T6.1, T6.2 and T6.3.

Within the workspace, there will be a separate discussion group foreseen for SHB members, where their conversations can be stored. This discussion group will only be visible to SHB members and T6.1, T6.2 and T6.3.

Within the workspace, there will be also discussion groups for SF members grouped per type of stakeholder (such as regulators, technical support organisations (TSO), medical professionals, patient organisations, as well as industry delegates). This discussion group is only visible for the specific SF group members, T6.1, T6.2 and T6.3.

The T6.2 leader will provide the credentials to the members of the SHB and SF to access the workspace (and the partners in T6.1, T6.2 and T6.3). These credentials are personal and linked to specific access rights according to the specific roles of the SHB and the SF members.

WP6 administration

SHB members costs reimbursement process

IRSN will reimburse the costs related to the participation of members in SHB meetings according to the following conditions:

- As far as air tickets are concerned, SHB members will forward their wishes to the WP6 leader and IRSN will directly book the air tickets that will be sent by email to the participants.

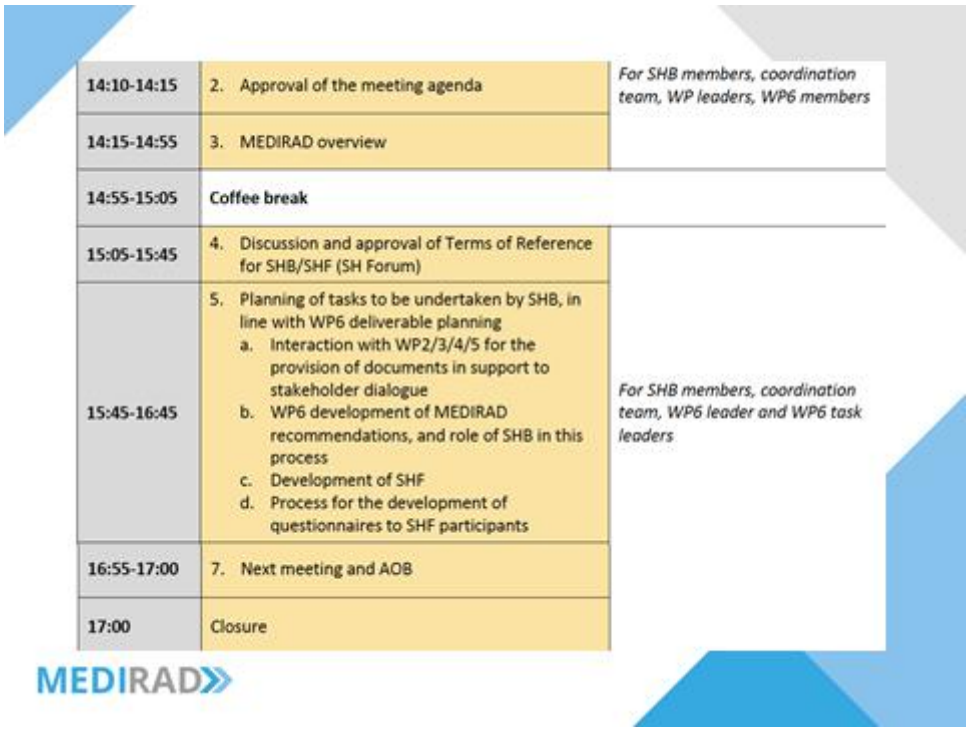
- For other expenses, IRSN will reimburse SHB members on the basis of the original invoices to be sent to the WP6 leader.

Procedure for nominating or replacing SHB/SF members

SHB members are respectively appointed by the following organizations: ESR, ESTRO, EANM, EFOM, EFRS, EPF, MELODI, EURAMED, EURADOS, WHO. The SHB is chaired by Jacques Repussard, acting as an independent expert.

In consultation with the MEDIRAD SHB and MEDIRAD Scientific Advisory Board (SAB), EIBIR will establish and keep up-to-date a database of a maximum of 150 stakeholder representatives who will be invited to participate in the Stakeholder Forum (SF).

4.5 Annex 5: Agenda of the first SHB meeting



14:10-14:15	2. Approval of the meeting agenda	*For SHB members, coordination team, WP leaders, WP6 members*
14:15-14:55	3. MEDIRAD overview	
14:55-15:05	**Coffee break**	
15:05-15:45	4. Discussion and approval of Terms of Reference for SHB/SHF (SH Forum)	
15:45-16:45	5. Planning of tasks to be undertaken by SHB, in line with WP6 deliverable planning a. Interaction with WP2/3/4/5 for the provision of documents in support to stakeholder dialogue b. WP6 development of MEDIRAD recommendations, and role of SHB in this process c. Development of SHF d. Process for the development of questionnaires to SHF participants	*For SHB members, coordination team, WP6 leader and WP6 task leaders*
16:55-17:00	7. Next meeting and AOB	
17:00	Closure	

MEDIRAD

4.6 Annex 6: Approved minutes of the first SHB meeting

Project title: Implications of Medical Low Dose Radiation Exposure

Grant Agreement Number: 755523

Call identifier: NFRP-2016-2017

Topic: NFRP-9

Annex 6 to Deliverable D6.1

Minutes of the First Stakeholder Board Meeting

13 April 2018 (13:30-16:30), Rome, Italy

Final Version (14 May 2018)

Participants:

- Members of the SHB: Jacques Repussard (Chair), Sisko Salomaa (MELODI), Željka Knežević (EURADOS), Viktoria Fonsou (EPF), Maria del Rosario Perez (WHO), Reinhard Loose (ESR), Christoph Hoeschen (EURAMED).
- MEDIRAD WP representatives: Elisabeth Cardis (WP1), Guy Frija (WP1), Monika Hierath (WP1), Ulrike Mayerhofer-Sebera (WP1), John Damiliakis (WP2), Glen Flux (WP3), Isabelle Thierry-Chef (WP5), Jean-René Jourdain (WP6, Task 6.1), Nathalie Impens (WP6, Task 6.2), Filip Vanhavere (WP6, Task 6.3), Jonathan McNulty (WP6, Task 6.3), Antonella Rosi (WP6, Task 6.3), Alessandra Palma (WP6, Task 6.3), Sveva Grande (WP6, Task 6.3), Cinzia De Angelis (WP6, Task 6.3), Sara Della Monaca (WP6, Task 6.3).

Apologies were received from Virginia Tsapaki (EFOMP), Anders Widmark (EFRS), Gerhard Glatting (EANM), Wolfgang Doerr (ESTRO).

1. Introduction

As an introduction, Jacques Repussard reminded that the members of the SHB have been nominated to represent the European radiation protection research platforms of interest for MEDIRAD (MELODI, EURADOS, EURAMED), the European medical associations (ESR, ESTRO, EANM, EFOMP, EFRS), and the European patient associations (EPF). Beside the SHB will be the stakeholder forum (SF), which will

consist of a group of maximum 150 people representing different communities from different European countries, with whom the SHB will dialogue on MEDIRAD recommendations that will be drafted. As they are consultative bodies, Jacques Repussard emphasized that the MEDIRAD SHB and SF will not approve formally these recommendations. The recommendations will be formal deliverables to the European Commission and will undergo the formal consortium internal review/revision procedure prior to submission.

2. Approval of the meeting agenda

Jacques Repussard presented shortly components of the agenda of the meeting that participants approved.

3. MEDIRAD overview

Jean-René Jourdain presented a summary of the objectives of each MEDIRAD WP as they are described on the MEDIRAD website and then called for questions from the participants.

WP1:

- Sisko Salomaa asked about the missions of EIBIR. Monika Hierath answered by describing briefly the role and activities of EIBIR.
- Guy Frija asked if MEDIRAD WP1 can contribute to the MEDIRAD recommendations' drafting. Jacques Repussard answered positively.

WP2:

- Jacques Repussard asked from what stage the material necessary for the MEDIRAD recommendations' development will be mature enough to be used for that purpose. John Damiliakis emphasized the rather complicated architecture of WP2 that comprises 4 tasks and many subtasks. Most of the subtasks will provide results certainly relevant for the recommendations' development. However each subtask should be discussed separately to decide on whether the results could be used for the recommendations and when they will be available.
  Jacques Repussard answered that it would be helpful to identify for each MEDIRAD WP a tentative list of subtasks that are potentially of interest for drafting the recommendations.
- Maria Perez asked for clarification on how the WP2 results will serve for the recommendations. John Damiliakis described shortly the structure and objectives of WP2: the main objective of Task 2.1 is to optimize chest CT examinations through the development of a web-based tool capable of determining the optimal chest CT protocol based on the relation between clinical indication, required image quality and lowest achievable patient radiation dose. The outcomes of this task will probably not be useful for the recommendations. Mainly Task 2.2 (optimisation in fluoroscopically-guided interventional procedures) and Task 2.3 (dose evaluation and optimisation of multimodality imaging) will provide inputs for the development of recommendations.
  Jacques Repussard invited WP leaders to think in terms recommendations, not only towards professionals, but also towards other communities such as regulators, recognizing that some tasks may provide relevant information for more general recommendations directed to regulators. He emphasized that all the work of MEDIRAD should be used as much as possible.

Sisko Salomaa pointed out that recommendations may consider also how to organize research, how to improve the quality of research, how to better collaborate at the European level etc. She mentioned the example of the creation of the initial dose biobank.
Christoph Hoeschen mentioned the example of the relation between dose and image's quality. Research should be developed in a way that can be translated into practice and that will serve a better harmonization and improvement of practices.

- John Damiliakis asked about the length of the recommendations. Jacques Repussard answered that the recommendations should be readable by people outside of research, in other words people knowledgeable but not expert. He indicated a length of 5-10 pages as a rough guide.
  Jean-René Jourdain pointed out the need to define a template common to all recommendations. As soon as such template is developed and as soon as WP6 has a clearer view on what type of material and when it will be available for the recommendations, WP6 Task 6.3 leaders will be able to develop such template. He reminded that the recommendations will consider also the views of a wide range of stakeholders, including those not familiar with radiation protection research, and that they will be publicly available, highlighting the need to draft recommendations adapted to the diversity of targeted audiences (scientists, patients, authorities, etc.).
  Jacques Repussard emphasized that a recommendation is very different from a scientific publication because the recommendations should reflect a large consensus and should leave out fragile conclusions. MEDIRAD recommendations should not consider controversial stuff that would attract immediate criticism.

WP3, WP4:

No question from the assembly.

WP5:

- Isabelle Thierry-Chef informed the participants she's confident in the capacity of WP5 to provide on due time results relevant for the MEDIRAD recommendations.

WP6:

- Jacques Repussard mentioned the objective of developing a draft structure that would serve as a template for each recommendation. WP6 partners are responsible for producing this document that will be then submitted to the consideration of other MEDIRAD WP leaders and SHB members.
- As for the SHB's role, Elisabeth Cardis asked what does mean « *the SHB will analyse the MEDIRAD recommendations by considering their content relevance and consistency* ». Jacques Repussard clarified that the process is a consultative process; at the end the decision will always go to the MEDIRAD Executive Board, and not to the MEDIRAD stakeholder board. Indeed the MEDIRAD bodies (Executive Board, General Assembly) can ignore the SHB's recommendations, but in such a situation they will have to explain why.
  Maria Perez insisted on the need to clarify whether the SHB is a decision-making board or a consultative board, referring her question to the sentence "*the SHB will decide on the composition of the stakeholder forum*". Jacques Repussard answered that the SHB is a consultative board. Concerning the specific issue of the stakeholder forum composition, he clarified that the SHB will initiate the process by establishing a list of potential members of the stakeholder forum; for that purpose each body represented within the SHB will propose a list of 20-30 members/organizations from different EU Member States to be part of the

stakeholder forum. Then the resulting list of 150 members of the stakeholder forum will be forwarded to the MEDIRAD Executive Board.

Jacques Repussard also mentioned that the stakeholder forum will not include commercial companies, which doesn't mean that industry will be excluded from the MEDIRAD stakeholder forum. Thus associations/institutes/groups representing without conflicts of interests industrial companies, and which are used to dialogue with institutions like the European Parliament, will have the opportunity to contribute to the stakeholder forum too.

To conclude on that point, Maria Perez suggested rephrasing the sentence "*the SHB will decide on the composition of the stakeholder forum*" as follows: "*the SHB will advise on the composition of the stakeholder forum*".

- Maria Perez emphasized that the recommendations will be MEDIRAD recommendations, which doesn't mean that SHB members will necessarily endorse them, as SHB members will serve as advisors only.
- Still as for SHB's role, Christoph Hoeschen made a comment on the sentence "*the SHB will coordinate the MEDIRAD stakeholder related activities*". Indeed the SHB will advise the MEDIRAD members, however it will not have the power to coordinate the MEDIRAD stakeholder related activities. Jacques Repussard answered that the role of SHB, interfacing with the stakeholder forum, is a little bit more than advising. Actually, even though the SHB cannot impose its views to third parties, nevertheless the SHB will support the coordination of MEDIRAD stakeholder related activities by helping the consortium to interact with the concerned stakeholders. Nathalie Impens emphasized that the SHB may help MEDIRAD by advising the consortium for example on what questions should be asked to the stakeholder forum. For that purpose, the workspace that is being developed at SCK•CEN in Task 6.2 will certainly contribute to the coordination of these activities.

  Jean-René Jourdain added it is of the responsibility of the SHB to check that the MEDIRAD recommendations will meet the objectives initially defined. In addition, the SHB will have to ensure that the recommendations are written in a form adapted to the public for whom they are intended (e.g. medical communities for recommendation #2, or policy makers and competent authorities for recommendation #3, or research communities for recommendation #4).
- Taking a point that Anssi Auvinen made in the frame of the SAB meeting, Sisko Salomaa asked how the recommendations could be developed before the end of the project, especially if no results are available. Also she asked whether WP6 partners have thought about the publication of recommendations in peer review journals. Jacques Repussard answered that WP6 partners should not wait for results to start the development of recommendations. He invited WP6 partners to start working by thinking right now about possible existing material that could be used for the development of recommendations, which will be fed further thanks to the results obtained along the course of the project. As for the second question, Jacques Repussard emphasized the need not to confuse recommendations and scientific publications.
- Maria Perez asked if SHB members are expected to provide inputs for the development of the stakeholder survey. Nathalie Impens answered that WP6 members need to have the SHB's recommendations on the type of questions that should be raised within the web-survey.

  Jacques Repussard added that the SHB is expected to provide advises and ideas, but the questions themselves will be drafted by WP6 partners.
- To conclude the discussion on WP6, Jacques Repussard asked the coordination team to avoid scheduling next SHB meetings on a Friday afternoon (suggestion supported by Reinhard Loose).

4. Discussion on terms of reference for the MEDIRAD stakeholder interface structure

Jean-René Jourdain presented briefly the structure of the draft document and then SHB members were invited to review it section by section and formulate their comments, which are summarized below.

- Background: Reinhard Loose suggested abbreviating "Ionizing radiation" by "IR".
- WP6 composition and task structure:
    - WP6 partners were asked to update the list of their representatives.
    - Nathalie Impens suggested adding the Task leaders' emails. Rather than doing so, Jacques Repussard suggested writing a sentence stating that all communication should be made preferentially through the workspace set up by SCK•CEN for MEDIRAD stakeholder activities.
- Stakeholder board membership:
    - Jacques Repussard suggested removing from the document email addresses of SHB members.
    - Elisabeth Cardis asked if this document is a public or private document. Jacques Repussard answered that it is a document restricted to the stakeholder forum and board members (Note: the final version of the ToR will be available on the MEDIRAD teamwork platform for all consortium partners).
    - Maria Perez and Jacques Repussard agreed to name the WHO representative as "*special adviser*".
    - Christoph Hoeschen asked how will be managed possible changes in the composition of the SHB along the course of the project. Jacques Repussard suggested adding a paragraph stating that the initial intention was to have representatives of each pertinent association/organization (European medical societies, European radiation protection research platforms, European patient associations, WHO), so that people will be aware of the rationale that was behind the nomination of SHB representatives in case one or several names change.
    - Maria Perez pointed out that SHB members represent their association/organization and are not nominated *intuitu personae*.
- Mission, Role and responsibilities of SHB members: These texts have been modified to take on board the comments made by the members of the SHB during the discussion that followed the presentation of WP6 (see paragraph 3 of this document).
- Ethics of stakeholder dialogue:
    - Maria Perez stated that the SHB and SF will not "*develop and observe MEDIRAD ethical guidelines*". Elisabeth Cardis suggested writing "*comply with relevant ethical principles*".
    - Maria Perez suggested adding the prevention of conflict of interests as an example of ethical principle.
- WP6 administration:
    - Jean-René Jourdain presented briefly the rules governing the reimbursement of costs related to the participation of members in SHB meetings (e.g. air tickets booked by IRSN, reimbursement done on the basis of original invoices to be sent to WP6 leader) and asked SHB members to provide him as soon as possible with their bank account details (including IBAN and SWIFT/BIC code).
    - Ulrike Mayerhofer-Sebera asked whether the SHB and SF members will have to sign a confidentiality disclaimer. Jacques Repussard answered it is not really feasible and

suggested adding such a disclaimer in every document that will circulate among SHB and SF members (e.g. draft recommendations).

5. Planning of SHB tasks

Jacques Repussard proposed to prepare a note explaining the process of MEDIRAD recommendations' development (why, how, when, etc.), including a template architecture that will form the backbone of each recommendation.

Jacques Repussard reminded that each SHB member is invited to propose a list of stakeholders (e.g. associations, NGOs, etc., but not individuals) in the scope of competences of the body that each member represents within the SHB. Maria Perez suggested starting with a big list as a first approach, which will be then cleaned up by considering issues like geographical distribution (it is noted that non-European stakeholders may be considered too) or competences, etc. Victoria Fonsou suggested individuals with patient expertise and access to broad networks (formal and informal) should be included in the SF as there is a need for valuable and impactful patient input of living with a disease and dissemination of research results among their networks.

→ **Deadline for this action: end of May 2018 (contact and responsible partner: EIBIR as Subtask 6.1.2 leader)**.

As for the deliverable 6.2, which is due by end of May 2018 according to the MEDIRAD description of action ("Report on the Stakeholder Forum: composition, content of the web-consultation, guidelines for the use of the stakeholder infrastructure"), recognizing that the forum composition will certainly not be available by end of May 2018, it has been agreed to present in the report a text outlining how stakeholder forum will be set up and how its members will be identified.

As for the development of questionnaires to be sent to stakeholder forum participants, Jacques Repussard proposed to organize a web-meeting in June 2018 to discuss deeper this point. EIBIR is tasked to organize this meeting.

6. Next meetings and AOB

The next SHB meeting will be scheduled in spring 2019 in a location to be decided shortly by the MEDIRAD coordinator.