MEDIRAD

RECOMMENDATION 1

CONSOLIDATION OF PATIENT DATA REPOSITORIES ACROSS EUROPE

PROJECT TITLE

Implications of Medical Low Dose Radiation Exposure

This project has received funding from the Euratom research and training programme 2014–2018 under grant agreement No 755523.

About MEDIRAD Recommendations

MEDIRAD is a research project funded by EURATOM under Horizon 2020 Programme (2016/ 2022). Bringing together radiological and clinical research teams from several European countries, it aimed to enhance the scientific basis and clinical practice of radiation protection in the medical field, in particular by better understanding and evaluating the health effects of exposure to low doses of ionising radiation resulting from diagnostic and therapeutic applications. MEDIRAD was designed to have direct implications for the radiological safety of European patients undergoing medical imaging and therapy procedures involving ionising radiation, and of exposed medical professionals. For this purpose, one of the goals of MEDIRAD was to establish evidence-based consensus policy recommendations for enhancing the effective protection of patients and medical professionals, as well as for identifying further research priorities.

The scientific basis for the following recommendation stems from the research developed in the course of the MEDIRAD project. In order to achieve a sufficient degree of consensus, MEDIRAD engaged in a substantial dialogue with relevant stakeholders in Europe and internationally. The MEDIRAD Stakeholder Forum, which underpinned this dialogue, included representatives from 86 organisations who were invited to express their views on issues to be considered as priority, and to comment on the draft formulation of MEDIRAD recommendations.

MEDIRAD Recommendations are made publicly available under the sole authority of the MEDIRAD Consortium. More information on MEDIRAD is available in Annex 3.

Competent international organisations, public authorities at European and national level, and organisations such as European research platforms and professional or patient associations, are invited to consider these recommendations and engage or support actions towards their implementation as they see fit, taking the opportunity of initiatives such as the SAMIRA (Strategic Agenda for Medical Ionising radiation Applications) European Action plan.

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Introduction

Patient data repositories are an essential source of information both for optimising patient treatment and follow-up and for improving scientific understanding of effects of medical radiation exposure. This set of recommendations is based on the experience acquired through the MEDIRAD project (see Annex 1), and addresses two fundamental and challenging aspects related to the consolidation and use of patient data repositories across Europe: adequate storing of the data, the access to such data for research purposes in a manner that protects them according to current regulations (i.e. the General Data Protection Regulation).

Access to an organised collection of clinical image and dose data at the European level, suitably coded to effectively protect the patients' identities, is of utmost importance to advance radiation protection research, clinical practice, and personalised medicine. Such an infrastructure enables the collection, storage, and retrieval of image and dose data, together with essential clinical / patient data, offering a means by which to efficiently conduct large-scale multinational epidemiological studies, benchmark clinical practice, and optimise patient care through precision medicine [1]. Furthermore, image and dose data repositories are an essential resource for developing artificial intelligence (AI) solutions that hold the potential to revolutionise medical applications of ionising radiation, including medical imaging, nuclear medicine, radiotherapy, and integrated diagnostics [2]. The current unavailability of a robust and efficient interconnected system of repositories represents a major barrier to the clinical translation of ionising radiation research, which must be urgently addressed, a conclusion that is supported by the findings of a recent Delphi study conducted within the EURAMED Rocc-n-Roll project [3]. However, the creation and upkeep of such repositories is an expensive, resource intensive and lengthy investment, particularly given the heterogeneity of imported data and associated data sources [4].

Therefore, it would be greatly beneficial to develop an interconnected image and dose repository system at the European level, guaranteeing patient data protection, featuring standardised characterisation of data sets and which could be maintained over time and remain accessible for numerous research and innovation projects. Such a system could also have subsequent impact at the European and global level.

Biomedical and radiation protection research increasingly relies on personal data pertinent for the analysis of exposure / health effects associations. Access to and exploitation of such data is regulated by the General Data Protection Regulation (GDPR) Directive [5], which was implemented, with national variations between European countries, in 2018. Such variations present high difficulties for European research projects that require access to, and exploitation of, personal data across several countries (e.g. epidemiological studies, biobanks, dosimetric and imaging repositories, etc.). Efforts to harmonise regulatory practice should be encouraged, notably through the collection of experience gathered through EURATOM research projects. Other EU initiatives on GDPR implementation have been launched, including the European Health Data Space [6,7].

The MEDIRAD project started in June 2017, whereas the GDPR came into effect in 2018. Accordingly, the project had to adapt procedures involving utilisation of patient data for its scientific investigations. The objective of the following recommendations is to facilitate the development of large-scale multinational epidemiological studies, by proposing guidelines to help European countries implement European regulatory requirements on ethics (including compliance with GDPR Directive). Guidance should be available for helping research projects to manage the GDPR rules but should be regularly reviewed and improved to take into account lessons learnt, the evolution of regulatory practice in member states, and the developing jurisprudence at the European level.

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European imaging and dose repositories.

Overall recommendation

Develop an interconnected and sustainable system of image and dose repositories at the European level.

» **Specific recommendations:**

1. Encourage the long-term development and maintenance of an interconnected system of key imaging and dose repositories.
2. Develop comprehensive guidelines for repository development, maintenance, and operation, in adherence with the framework and based on principles of data quality, robust and standardised infrastructure, and interoperability.
3. Support the development of European / international standards (coding schemes and structured reporting templates) for clinical practice.
4. Encourage the research community and practitioners to utilise structured data capture and reporting in medical imaging through European Commission based recommendations.
5. Support education and training initiatives to increase competency, harmonised implementation, and adherence to DICOM standards within industry.
6. Request transparency regarding the workings and dependencies of commercial tools.
7. Encourage the use of an application programming interface (API) in imaging and dose repositories and the continued development of meta-analysis tools to optimise data upload and analysis, respectively.
8. Encourage open-source repositories wherever manageable.
9. Encourage and support the interoperability of biobanks with image and dose data repositories, considering existing recommendations and infrastructure.

1.1. Justification

Within the MEDIRAD project a multinational, centralised, and integrated imaging and dose data repository, the Image and Radiation Dose BioBank or IRDBB, was constructed to support the research conducted across the project's 14 participating countries and research-centred work packages. More specifically, the repository was created as an integrated system comprised of both a DICOM data repository, suitable for managing radiological images and radiation dose structured reports, and a resource description framework (RDF) repository, supporting the semantic (i.e. ontology-based) descriptions of both DICOM and non-DICOM data, all accessible via optimised web-based application programming interfaces (API).

In this way, CT images and corresponding dosimetric data, along with associated metadata (demographics, clinical study descriptors, processing procedures, etc.) could be uploaded from multiple clinical studies and geographic locations for central storage, retrieval, and query with relative ease.

The MEDIRAD IRDBB thus provides proof-of-concept of an EU-wide repository for radiation research. Based on this experience, as detailed in Annex 1, the following science-based policy recommendations have been drawn in an effort to advocate and facilitate the further development of a European interconnected system of imaging and dose repositories for patients exposed to ionising radiation.

1.2. Implementation

1. Encourage the long-term development and maintenance of an interconnected system of key imaging and dose repositories.

Development and maintenance of imaging and dose repositories is a very resource intensive and costly investment, requiring an estimated €1-1.5 million per annum for their maintenance and growth; the upfront costs of constructing such an infrastructure can be even higher. As a means of exploiting the vast benefits of radiological repositories in a cost-effective and sustainable manner, it is recommended that an interconnected system of key imaging and dose repositories be set-up and maintained for years / decades as a critical research and development infrastructure accessible to research projects of all sizes throughout Europe.

Moreover, in order to avoid dispersion of efforts, it is recommended that existing repository initiatives be consolidated where practicable and linked with other repositories beyond the scope of ionising radiation research as part of the broader European Health Data Space for maximum impact [6].

To this end, a minimum 0.5% of Euratom annual research funding should be allocated to further developing, sustaining, and improving a robust and efficient repository network. In this way, the value of big data for clinical practice, epidemiological studies, AI / machine learning, quality control, and optimisation of patient care and follow-up (among other applications in medical radiation research) can be maximised while overhead costs are minimised.

» Target audience: Euratom authorities, public health authorities, medical professional organisations, research communities.

2. Develop comprehensive guidelines for repository development, maintenance, and operation, in adherence with the framework and based on principles of data quality, robust and standardised infrastructure, and interoperability.

The legal framework currently governing image and dose data repositories should be clearly outlined through a comprehensive central document with links to all relevant regulations and legislation (e.g. GDPR) to provide a central resource for repository developers, managers, and users, as well as the general public. Based on this, comprehensive guidelines should be developed for repository development, maintenance, and operation, promoting adherence to relevant regulations, legislation, international standards of practice, and the principles of the European Health Data Space [6].

These guidelines are to be developed in consultation with all actors (patients, industry, academia, etc.) involved in the development, maintenance and/or use of such repositories to ensure they address the needs of each group and effectively support them in overcoming barriers to regulatory adherence, high-quality data, standardised infrastructure, and information exchange. Of critical importance is the need for all repositories to have a quality assurance programme which ensures data sets meet quality requirements clearly specified within the legal framework and accompanying guidelines. Guidelines should also facilitate adherence to defined standards of practice and harmonised procedures where applicable. In this way, interoperability can be achieved, and the validity of associated research outputs / products better assured.

» Target audience: Euratom authorities, regulatory authorities.

3. Support the development of European / international standards (coding schemes and structured reporting templates) for clinical practice.

The successful implementation of an interconnected and sustainable system of imaging and dose data repositories, together with essential clinical / biological patient data, requires interdisciplinary cooperation and harmonisation efforts. It is crucial that radiation protection and clinical research teams across Europe work together through joint programming and research relevant to both parties in order to meet the urgent need for accessible, well organised, and representative big data. As we work towards increased standardisation for mass pooling of data sets, changes will be required. These changes must be accompanied by robust user-friendly tools that ease the burden on those involved at the operational level (e.g. clinicians), thereby facilitating the practical implementation and wide-spread adoption of such standards.

The main opportunities for cooperation and harmonisation are outlined below.

• Support / fund the development of improved coding schemes for clinical imaging procedures.

While current international standards, such as DICOM SR-concept and RadLex, provide solutions to much of the variability that exists in radiological reporting, there is an unmet need for increased precision when categorising imaging procedures, which could be achieved with a more comprehensive set of modifiers. To ensure the usefulness of repositories, a complete and standardised collection of procedural descriptors should be developed, frequently reviewed, and regularly updated by international organisations to allow for distinct aspects of radiological procedures, such as level of radiation (low-dose-protocol vs. standard-dose-protocol) and contrast phases (e.g., arterial / venous / late) to be reported in an internationally harmonised manner. The issue of imprecise categorisation is partly resolved by the LOINC/RSNA Radiology Playbook. However, a more exhaustive set of modifiers is required to reach the full potential of imaging and dose repositories. Thus, improved systems for categorising imaging procedures should be a priority item for inclusion in future research and development roadmaps. In parallel, software tools that facilitate implementation of the coding schemes into everyday clinical work-flows should be developed for maximum utility. Ideally, this would be coordinated at the EU or international level by organisations such as EURAMED, to best ensure harmonisation.

• Support / fund expert networks for the development of structured reporting templates for clinically relevant procedures.

The adoption by clinicians of structured reporting templates that incorporate standardised coding schemes is of critical importance for consolidating imaging and dose data repositories. Building upon the template developed in MEDIRAD, templates focused on a set of pertinent clinical procedures should be developed, frequently reviewed, and regularly updated by expert working groups led by pertinent scientific societies at the national, European, and international levels. Therefore, funding and support for European-based initiatives complementary to the RSNA RadReport Template Library is essential for the development of European-level repositories.

» Target audience: public health authorities, medical professional organisations, scientific communities, industry, clinicians, and practitioners.

4. Encourage the research community and practitioners to utilise structured data capture and reporting in clinical imaging through European Commission based recommendations.

Structured data capture and reporting will greatly facilitate the consolidation of Europe-wide data into large-scale registries. To this end, Euratom guidance documents will be needed to encourage their implementation. Furthermore, the quality and completeness of imaging / radio-therapy reports should be improved by future research and technology development programmes. Structured reporting should focus on a set of clinically relevant procedures (e.g. CT for pulmonary embolism, Cardiac-CT, oncological imaging, head and neck radiotherapy, thyroid ablation, etc.) to streamline implementation and use [8]. Where applicable, currently available international standards should be utilised and enforced.

These solutions include DICOM SR-concept, IHE MRRT profile, and SNOMED CT for general coding, as well as RadLex for radiology specific terms.

» Target audience: Euratom authorities, regulatory authorities, research community, practitioners.

5. Support education and training initiatives to increase competency, harmonised implementation, and adherence to DICOM standards within industry.

As the international standard for communication and management of medical imaging, DICOM is a cornerstone of information sharing in medical imaging and represents an essential element for creating the fully interoperable multi-vendor environment needed to develop, maintain, and use imaging repositories efficiently. Therefore, it is critical that all industry professionals / developers / manufacturers in the fields of diagnostic medical imaging, image-based therapies and associated research have a working knowledge of DICOM to assure interoperability between imaging / radiotherapy equipment and other systems, including repositories.

To this end, support to education and training initiatives that increase the competence of industry staff in this regard is highly recommended. Additionally, close collaboration between industry, academia, clinical practice, and the DICOM standards team should be encouraged, particularly when adapting standards to facilitate the incorporation of additional / novel data.

» Target audience: industry, medical professional organisations.

6. Request transparency regarding the workings and dependencies of commercial tools.

Industry partners play a key role in ensuring the utility and sustainability of an interconnected system of image and dose repositories. System integration, data consolidation, and overall workflow of a repository can be optimised by having, from the beginning of the project, full knowledge of the scope and workings of available tools, helped by the use of vendor-neutral terminology. Collaboration with and transparency from commercial vendors thus allows for the early detection of potential limitations that can be addressed and overcome during repository structure and coding scheme development. Such transparency is of particular importance when developing a system of linked repositories where the number of commercial tools is multiplied.

Therefore, it is recommended that the provision of clear documentation outlining the technical dependencies and required licensure associated with commercial equipment / tools be mandated by local, national, and international competent authorities, such as the European Commission Medical Devices Sector. Through these regulations, the effectiveness and long-term utility of imaging and dose repositories can be better ensured. Additionally, industry plays a central role in the implementation and wide-spread adoption of European / international standards and should develop technologies which integrate the use of harmonised terminology, quantities, units, etc., where available.

» Target audience: policy makers, regulatory authorities, industry.

7. Encourage the use of an application programming interface (API) in imaging and dose repositories and the continued development of proper meta-analysis tools to optimise data upload and analysis, respectively.

Incorporating an API in the repository structure enables larger volumes of data to be uploaded at one time, increasing efficiency of the system, and optimising clinical workflow. Additionally, meta-analysis tools and software packages that incorporate practical integrative tools and appropriate analysis techniques / models must continue to be developed to provide a more effective and user-friendly approach to conducting meta-analyses on large imaging and dose data sets. Comprehensive user guidelines should accompany all meta-analysis tools / software to ensure appropriate application and execution.

» Target audience: Euratom authorities, research communities, industry.

8. Encourage open-source repositories wherever manageable.

Repositories should be made publicly accessible wherever ethically and legally manageable, with special attention given to GDPR and associated legislation. This will, on one hand, facilitate the resources' wide-spread use, continued development, and increasing utility. It will also help ensure that clinical / research centres of all sizes have access to large, organised collections of high-quality image and dose data, thereby contributing to the advancement of radiation research. However, GDPR and the heterogeneous implementation of these regulations across EU member states puts constraints on open-source repositories.

A regulatory aspect requiring close consideration is the need for specific, informed, and unambiguous consent from an individual to use and store their personal data within the proposed system of repositories. Thus, efforts to enable open-source repositories should take into consideration the recommendations detailed in MEDIRAD Recommendation 1B section ('GDPR and Clinical Epidemiological Research') to help overcome these constraints. In the event open access is not feasible, intellectual property must be clearly defined and formally documented for all aspects of the repository, including future developments for the purposes of maintenance, use, and/or re-use.

» Target audience: health authorities, medical professional organisations, research community.

9. Encourage and support the interoperability of biobanks with image and dose data repositories, considering existing recommendations and infrastructure.

An interconnected system of image and dose data repositories should be compatible with other external repositories beyond the scope of medical imaging, nuclear medicine, and radiotherapy to maximise utility and impact. Biobanks (tissue and blood), for example, are an immensely valuable resource for advancing precision medicine and can play a major role in medical radiation and radiation protection research through a multisource integrative approach.

The biological samples housed within biobanks offer a wealth of information for clinical practice and for conducting robust clinical epidemiological, radiomic, and radiogenomic studies. To most effectively access and utilise available infrastructure in medical research, imaging and dose repositories and related biobanks should be developed with a goal of interoperability. To this end, it is recommended that EU / international organisations, as part of the forthcoming European Research Roadmaps from the EURATOM and HEALTH community, form dedicated working groups aimed at coordinating interoperability processes that are harmonised, collaborative and consider the infrastructures, outcomes and recommendations previously set forth by initiatives such as DoReMi, OPERRA, CONCERT, MELODI, BBMRI-ERIC, EURAMED, and most recently the European Health Data Space [6]. In this way, a robust network of harmonised health data can be implemented facilitating efficient information sharing and data consolidation.

» Target audience: research community, medical professional organisations.

1.3. MEDIRAD scientific achievements supporting recommendations

- Construction of an Image and Radiation Dose BioBank (IRDBB) across the 14 countries participating in the project, as proof of concept that an EU-wide repository for radiation research is feasible.
- Integration of different repositories in the IRDBB (DICOM and non-DICOM data).
- Optimisation of application programming interfaces (API) for uploading of and access to data from multiple clinical studies and geographic locations.

2

General Data Protection Regulation (GDPR) and Medical Radiation Protection Research.

Overall recommendation

1. **Harmonise GDPR implementation in medical radiation protection research.**
2. **Enhance the awareness regarding ongoing radiation protection research among public and patients.**

» **Specific recommendations:**

1. Set up a permanent group of experts at the European level.
2. Make extensive use of formal guidance documents that are reviewed and updated on a regular basis.
3. Promote the role of the data protection officer (DPO) among all institutions.
4. Organise and promote training courses on GDPR issues.
5. Ensure that the informed consent form about the use of personal data and biological samples is well written and clearly understandable.
6. Disseminate informative material about particular medical radiation protection research projects.

2.1. Justification

The MEDIRAD survey on problems encountered with the GDPR compliance process revealed that, for some MEDIRAD partners, the main difficulties were related to technical or procedural issues (related to the setting up of data protection measures but also procedural issues such as setting up training of personnel in GDPR), and with the lack of harmonisation of compliance rules among different countries or organisations.

Common guidance documents are intended to make the GDPR compliance process easier and more efficient. Their usefulness may be evaluated over time by periodically gauging the research community's opinion and making appropriate amendments and updates if needed. The survey also revealed that only one third of respondents used formal guidance documents (mainly national and in-house documents) for the management of GDPR protected data. A list of reference documents used by respondents is included in MEDIRAD RECO on GDPR Compliance Questionnaire Report (Annex 2).

The use of these documents was considered beneficial, underscoring the need to promote their use to streamline the compliance process. Support and advice from data protection officers (DPOs) from partner institutions, and other legal specialists, was also considered beneficial. Nonetheless, many researchers who completed the survey indicated poor knowledge of the existence of DPOs, indicating a lack of awareness and recognition of this profile. Researchers who completed the survey also expressed their willingness to improve their own knowledge and expertise in GDPR compliance issues.

Clinicians should also take into account that engaging with patients is not only a legal and ethical hurdle but is also a tool to raise patient awareness and trust in medical radiation protection research. The active involvement of the patients and, more generally, of the public in scientific research is nowadays considered of utmost importance both for the success of the research activity and for building the trust of the patients regarding the use of their personal data.

2.2. Implementation

1. Set up a permanent group of experts at the European level.

The group of experts on GDPR, composed by representatives of already existing national or local groups (e.g. those listed in Table 1 of Annex 2), belonging to research platforms in health related to Euratom research should guarantee a better and more efficient coordination between European countries, thus avoiding any divergence in the GDPR compliance process, through the drafting of guidance documents setting up common rules and procedures to implement, and comply, with the GDPR.

This group of experts should meet periodically with the scope of reviewing and updating common guidance documents (see next recommendation) and bringing together opinions and experience reported by the research communities from each country represented in the panel.

» Target audience: policy makers, regulatory authorities, research communities.

2. Make extensive use of formal guidance documents that are reviewed and updated on a regular basis.

The use of common guidance documents about GDPR compliance procedures can help harmonise the compliance process, and streamline the research activity of European projects, reducing setbacks and subsequent delays. Such documents should thus be consulted in the planning of medical radiation protection research projects in order to reduce differences in interpretation and practise. Some examples exist and can be found in Annex 2. These are intended to be living documents that are regularly updated by a group of experts (see previous recommendation) as well as a starting point for a fruitful dialogue between countries concerned.

» Target audience: medical professional organisations, research community.

3. Promote the role of the data protection officer (DPO) among all institutions.

Involve the DPOs of each partner institution from an early stage of the research project preparation and raise awareness among researchers about the existence and benefits of such experts. All institutional DPOs should be in contact with the DPO of the project itself in order to ensure that common procedures for GDPR compliance are followed by all partners.

» Target audience: medical professional organisations, research community.

4. Organise and promote training courses about GDPR issues.

Training courses should be organised at the national level, or within individual institutions, in order to brief researchers about GDPR issues when planning a research activity and/or setting up research infrastructures (database, biobanks, etc.). Courses should be delivered on national and international platforms in order to ensure the harmonisation of GDPR compliance mechanisms. They could also be required by law as normally happens for professional education and training. In particular, training of young people should be envisaged to guarantee correct education on GDPR issues from the beginning of their research careers.

» Target audience: research communities, industry.

5. Make sure that the informed consent form about the use of personal data and biological samples is well written and clearly understandable.

Increased awareness among patients about the scientific purpose of using their personal data will facilitate their decision to participate in a research project and to approve the use of their data for the project. Therefore, informed consent documents should be written in a comprehensible and accessible manner, with language that is accurate but not too technical. Clinicians should take time to carefully explain the objective and details of the specific research project, the need for patient data and biological samples, clarify any questions, and stress the procedures established to ensure security and the appropriate use of data and samples.

The ethical aspect linked to the use of personal data, samples, and images should also be explained i.e. that the research aims to benefit all patients in the future.

» Target: research communities.

6. Disseminate informative material about particular medical radiation protection projects.

As stated above, patients will be more willing to allow the use of their personal data if they understand the scope and purpose of the research project. Communication material such as flyers, social network content, infographics, and audiovisual material should be selected or prepared (if necessary) and shared with the public. Moreover, scientific outputs can be shared with the public through news stories and publications written in lay language. Engagement of patients and the public requires the allocation of budget specifically devoted to this activity in the research programme, and a case-by-case evaluation should be done to review the cost/benefit.

» Target audience: research communities, medical professional organisations, patient associations.

2.3. MEDIRAD scientific achievements supporting these recommendations

The main scientific achievements supporting the recommendations in Section 3 come from the MEDIRAD RECO on GDPR Compliance Questionnaire Report (see Annex 2 for detailed results). Overall, the survey reveals that researchers:

1. Are well aware about procedures to protect and manage patient's data.
2. Refer to EU, national and in-house documents for GDPR compliance.
3. Ask for harmonisation of compliance rules between different countries or organisations.
4. Lack knowledge of the role of the DPO in their institution and in the framework of the project.
5. Ask for training courses with common shared programmes on GDPR compliance.

3

Annex 1
Supporting evidence resulting from MEDIRAD research.

MEDIRAD Scientific Goals and Research Results

Coding and Structured Reporting.

Radiology departments use varying descriptions for imaging procedures (study names) with many national systems mainly used for billing. This variation limits the practicality of utilising the data produced from these procedures for research and quality assurance and presents a major barrier to establishing image and dose registries. To help overcome this variability in reporting, International standards and profiles are available for such processes, for example DICOM Structured Reporting objects or IHE MRRT-Profile (Management Radiology Reporting Templates). Different coding sets are also available, which include but are not limited to SNOMED CT for general coding in medicine or RadLex (by RSNA) for specific items in radiology.

Standards in coding and reporting offer several benefits, including:

- Structured data capture to ensure better quality and completeness of reports
- Validation while reporting
- Easier visualisation of pathological findings (e.g. display in another colour)
- The ability to combine medical findings and dose reports (DICOM RDSR)
- Coding schemes that enable categorisation of findings and comparison between different sites
- Structured reporting enabling pooling of reports (e.g. for research or epidemiological work-up)

As part of MEDIRAD, several catalogues for coding clinical studies in the MEDIRAD context have been developed based on RadLex [9]. For reporting, a standards-based reporting tool (MRRE) has been developed. This is based on the IHE MRRT profile to support coding, exchange of templates, and aggregation of results.

As an additional feature, a natural language processor (NLP) based check for consistency of the reports is included that allows for the comparison of requests from the clinical information with the findings and impression components of the reports. Additionally, dose reports for imaging studies (DICOM RDSR) can be combined with the reporting of the content itself, thus fulfilling European legal requirements. Additionally, the visualisation of findings can be improved, for example by highlighting pathological findings to be displayed in different colours. The reporting tool is fully integrated with the KHEOPS platform, which is used for the management of imaging studies in MEDIRAD.

Imaging and Dose Repositories.

A European level imaging and dose data repository, named the Image and Radiation Dose Biobank (IRDBB), was developed to enable the collection, storage, and retrieval of de-identified image and dose data relevant to the MEDIRAD project [10]. The IRDBB comprises three integrated components:

1. DICOM repository, that receives and stores the DICOM data (images and dose data) and provides query/retrieval to the end-users based on pre-existing open-source PACS software including structured reports (DICOM SR) and other DICOM-compliant data structures, such as exchange of dose data and technical parameters of the examination. The DICOM repository is capable of managing all imaging modalities considered in MEDIRAD.

2. DICOM import software, that interacts with data on the client's side, enables a zero footprint (no software installation on the client side), selects data to be sent to the central repository, ensures de-identification, on-the-fly lossless compression, and sends data to the central DICOM repository, with management of large volume transfer. Data transmission uses DICOM web services that facilitate communication over the web and across the firewalls of healthcare enterprises.

3. Semantic repository (referred to as RDF) for non-DICOM dose data. Unique identifier sets link the DICOM and RDF repositories. An application ontology has been created, covering the information domain specified by experts. Software has also been developed to populate the RDF repository, both from DICOM metadata and from data expressed in other ad-hoc formats.

The MEDIRAD project, under the guise of the IRDBB, as detailed above, has provided proof-of-concept for a regional patient dose and imaging registry within Europe. Following on from this initiative, the MEDIRAD consortium supports further research, development and wide-spread adoption of image and dose repositories for the purposes of optimising radiation protection research and patient care. Full reports on repository setup, piloting and catalogue development in the context of MEDIRAD can be accessed via the MEDIRAD website.

MEDIRAD RECO on GDPR Compliance Questionnaire Report

Drafted by **S. Della Monaca**, **V. Dini**, **S. Grande** e **A. Palma**, WP6

The online survey on GDPR Compliance developed by WP6 was launched on 01/02/2021 and closed on 28/02/2021.

We collected 37 answers from researchers, members of 21 different institutions and involved in WP 2-6 of the MEDIRAD Project (Questions 1-4, Figure 1).

Figure 1
Wich MEDIRAD Work Package(s) are you involved in?

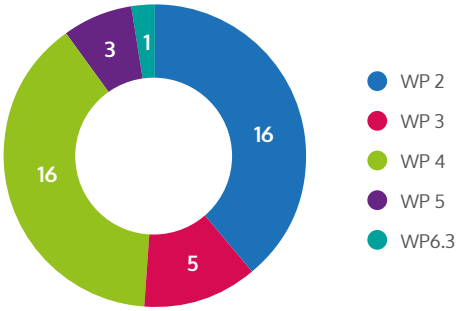
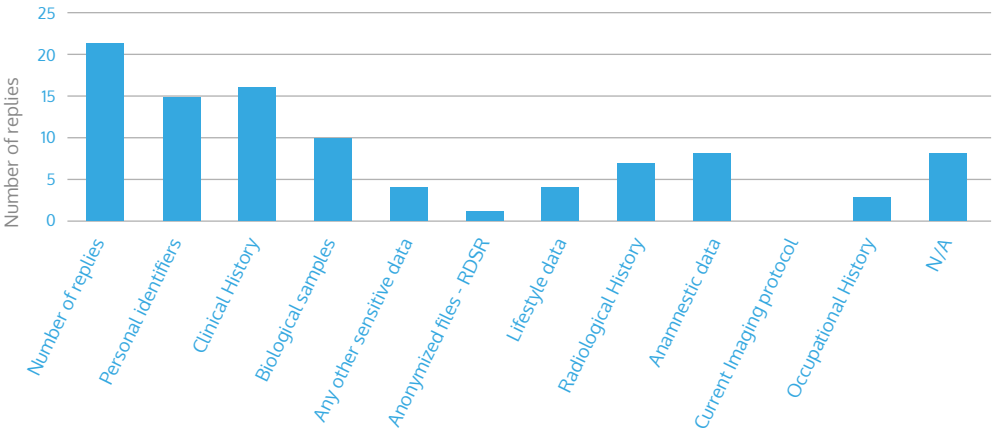


Figure 2
Type of nominative patient data collected

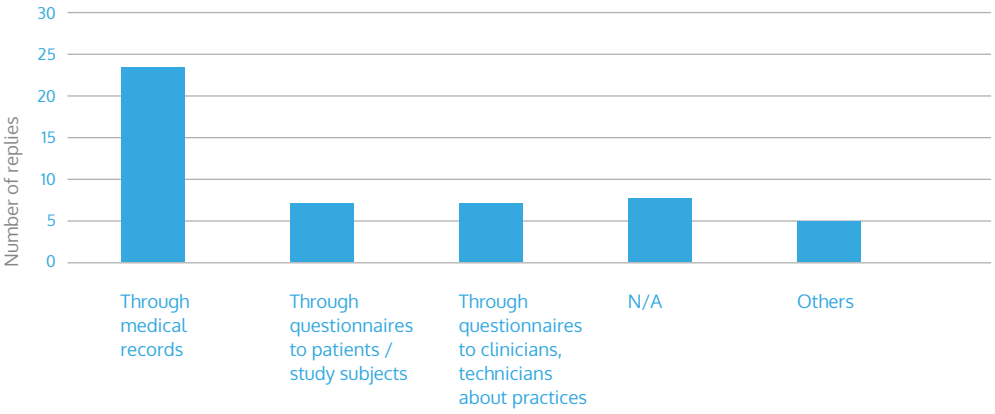


In Figure 2 the distribution of answers to question 5 are shown, i.e., how many respondents declared to collect each type of nominative patient data. Multiple answers were allowed. It comes out that the three most frequent type of data collected are Any type of clinical images (21/37 declared to collect them), Personal identifiers (15/37) and the Clinical history (16/37).

From question 6 (If you answer "Any other sensitive data" in the previous question, please specify) it comes out that Any other sensitive data are dosimetric data (two answers) or vital status data and cancer incidence data (one answer).

Figure 3 describes the distribution of answers to question 7 (How were these data obtained?) and it comes out that the most employed method to collect data is the Clinical registry (24/37). Other listed method (Questionnaires to patient/study subject and Questionnaires to clinicians, technicians about practices) were equally distributed and much less frequent (6/37 both). A few respondents (5) added other options, such as PACS, linkages with disease registries, through the International Regulatory Database (IRDB). Exactly the same respondents who answered N/A to question 5, coherently answered N/A to this question.

Figure 3
How were these data obtained?



Question 8 concerns what procedures have been set up for protecting MEDIRAD patient related data during storage, management, exchange, and processing. The question allowed multiple answers.

Figure 4 shows that 28/37 people have taken data protective measures, 25/37 relied on ethics approvals, 19/37 on informed consent and the 15/37 stated that patients have been informed of their right of access to their personal medical information stored in relation to the MEDIRAD project. The histogram suggests that several measures have been taken at the same time to ensure data protection.

Figure 4

What procedures have you set up for protecting MEDIRAD patient related data through storage, management, exchange and processing?

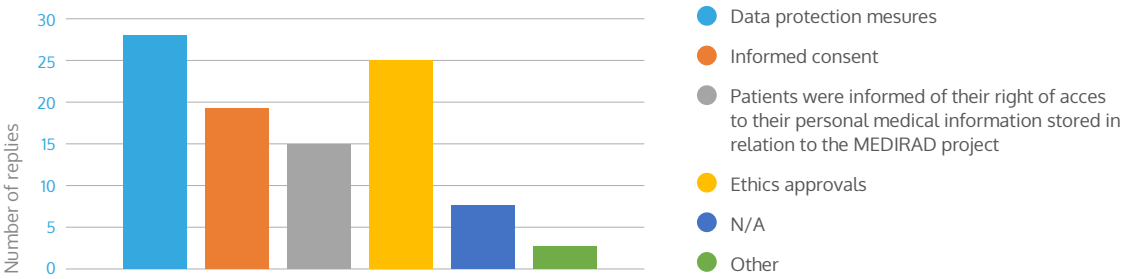
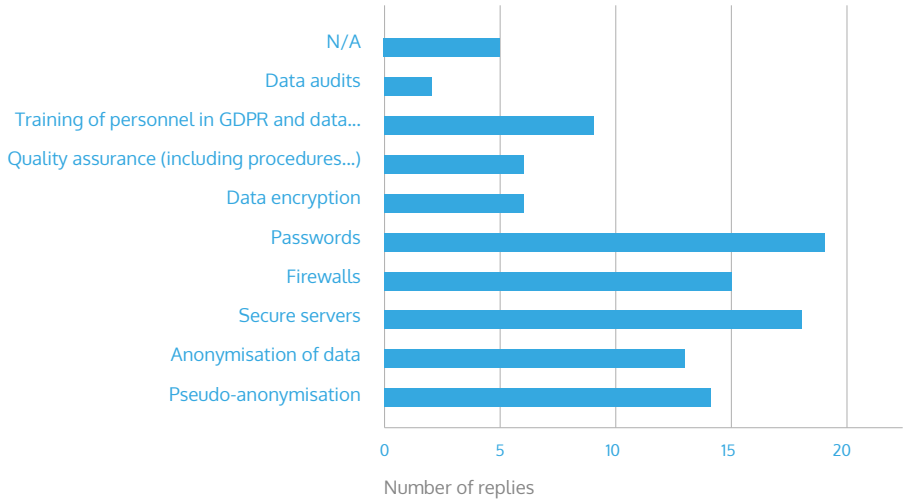


Figure 5

If you answer "Data protection measures" in the previous question, please specify.



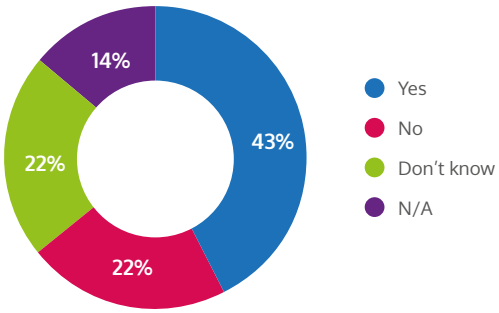
With regard to the Data protection measures, the main measures taken were password (19/37 people), secure servers (18/37 people), firewalls (15/37 people), pseudonymisation (14/37 people), and anonymisation of the data (13/37 people) (Figure 5). The other measures were adopted in lower numbers (from 2 to 9), and, in particular, the last one was audits (2/37 people).
Regarding the question 10 about Data protection procedures/measures we received only the following three comments:

- Seems that every clinical centre has its own understanding of the procedures to implement to comply with GDPR.
- The patient records arrive already anonymised to me.
- Patient anonymisation and imagine anonymisation sent to unique server.

Question 11 investigated whether a DPO had been appointed within the respondents's organisation as part of the MEDIRAD project (Figure 6). 43% of the answers are affirmative while the remaining 47% is distributed between No (22%), I don't know (22%), and Not Applicable (14%).

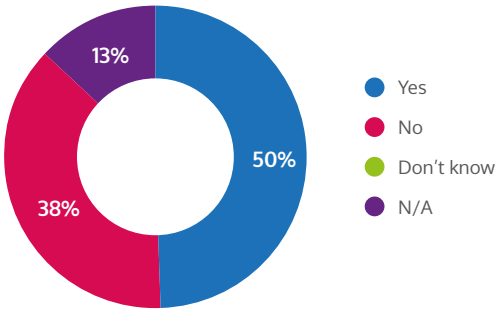
This data is quite significant, possibly indicating a lack of adequate information about GDPR compliance issues together with a lack of clarity in the way of the question was formulated. Possibly, to avoid ambiguity and maybe get less "I don't know" answers, a more suitable way of writing the question would be: Was the DPO operating in your organisation involved in your MEDIRAD research activity?

Figure 6
Are there nominated "data Protection Officers" (DPOs, as defined by GDPR) within your organisation in the context of MEDIRAD research?



People who answered Yes to Question 11 were then redirected to Question 12, in which they were asked if they had received support from their DPO. The percentages are shown in Figure 7. Again, a lack of clarity of the previous answer is evident also in this graph. Some of the respondents who declared to have involved their own organisation's DPO in the MEDIRAD activity stated that the issue of whether a support/advice was in fact provided is 'Not Applicable', which is quite unlikely.

Figure 7
If you answered "Yes" to the previous question, have you received support/advice from these DPOs?



Almost one third (32%,12/37) of the respondents affirmed to refer to formal guidance documents for the management of GDPR protected data in the framework of MEDIRAD project (Question 13, Figure 8). The nature of such guidance it is equally distributed between national and in-house documents; one respondent referred to EU documents (Figure 9, Question 14: this question allowed multiple responses).

Figure 8
Did you refer to formal guidance documents for the management of GDPR protected data in the MEDIRAD project?

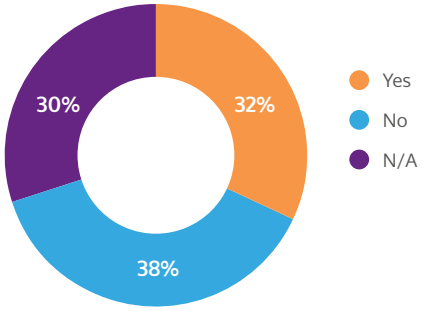
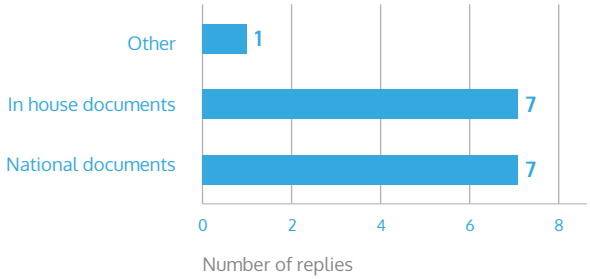


Figure 9
If you answered "Yes" to the previous question (13), pplease specify the nature of such guidance.



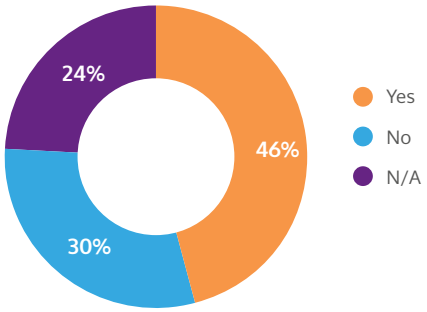
In addition to the use of GDPR, some in-house or national documents were cited by respondents. The references of such documents (Question 15) are reported in Table 1, together with the institution and the State of the corresponding respondent.

Table 1
ANSWER TO QUESTION N.15

Guidance documents	Institution	State
Wet Persoonsregistratie (WPR) Wet Geneeskundige Behandeloverenkomst (WGBO) Privacy Kader UMCG	University Medical Center Groningen	The Netherlands
In house GDPR guidance The Data Protection Act 2018	The Royal Marsden National Health Service Trust	UK
https://www.upc.edu/normatives/ca/proteccio-de-dades/normativa-europea-de-proteccio-de-dades/drets	Universitat Politécnica de Catalunya	Spain
Via ethical committee	Universiteit Gent	Belgium
Documents from the CNIL (Commission Nationale de l'Informatique et des Libertés)	Institut de Radioprotection et de Sûreté Nucléaire	France

Moreover, almost a half of the respondents declared to have benefit from oral guidance form their own organisation's DPO or other legal specialists (Question 16, Figure 10).

Figure 10
Did you also benefit from oral guidance from your organisation's DPO or other legal specialists?



No major impacts (some delays or even no notable impact) to ensure GDPR compliance in MEDIRAD activities have been reported by the majority of the respondents; however, the development of alternative solutions in order to ensure compliance or, even, the impossibility of carrying out a part of the research were declared by a minority of MEDIRAD researchers. (Figure 11, Question 17: this question allowed multiple responses).

Figure 11
What was the impact of GDPR compliance issues on your work in MEDIRAD?

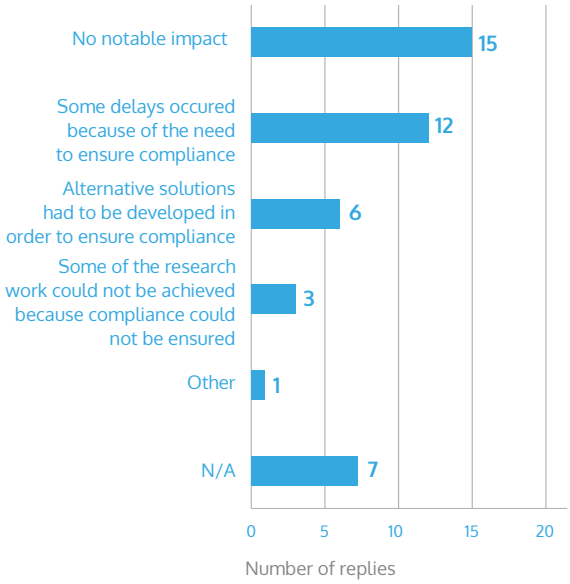
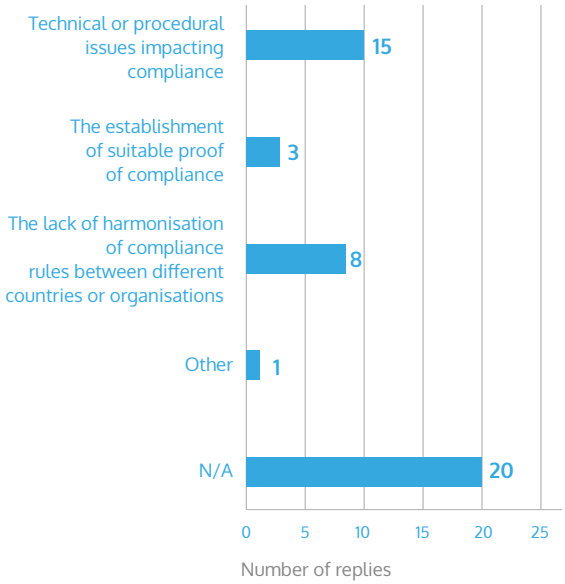


Figure 12
If difficulties with GDPR compliance occured, were these mainly related to:



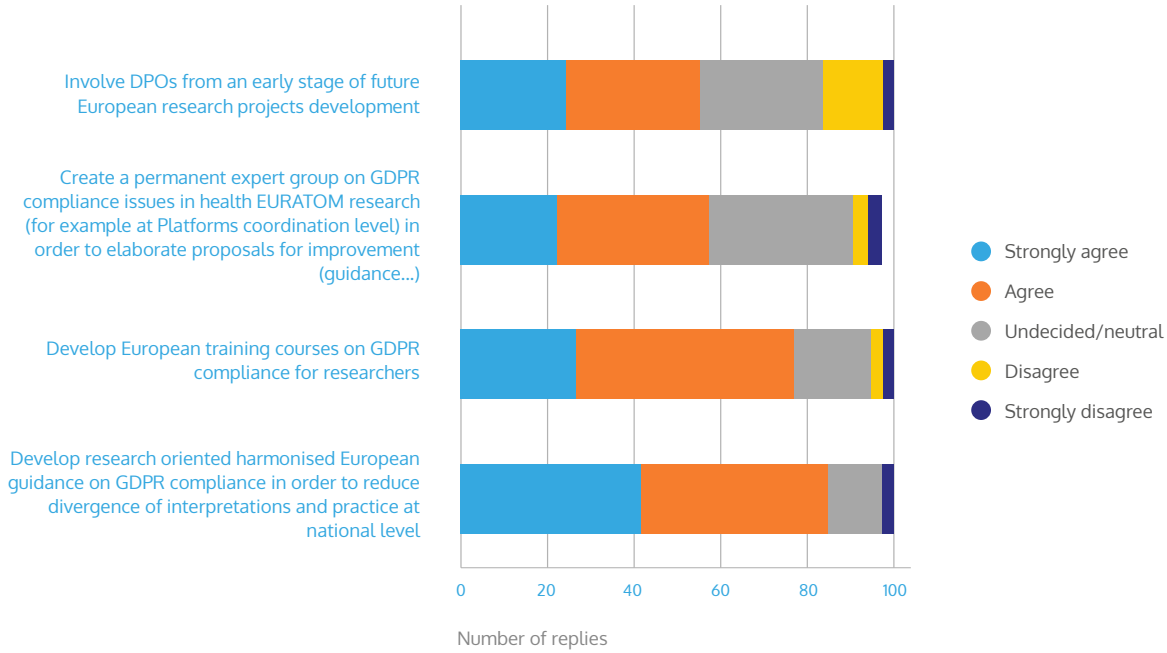
The difficulties with GDPR are mainly correlated with technical or procedural issues and with the lack of harmonisation of compliance rules among different countries or organisations. Most respondents, however, stated that they did not encounter any difficulties (Figure 11, Question 18: this question allowed multiple responses).

One researcher declared that patients who declined permission to get access to their medical file were withdrawn from the study. Moreover, another researcher declared that local partners (such as a local health agency) claim that they have no right to use the address to contact patients (cases and controls) (Question 19).

In the following, responses to the Questions 20-23 On the basis of your experience within the MEDIRAD project, please rank your agreement about the following suggestions for facilitating GDPR compliance in future health related European research projects (Ranking: 1. Strongly disagree; 2. Disagree; 3. Undecided/Neutral; 4. Agree; 5. Strongly agree) will be shown (Figure 13). Erroneously, Question 22 was set as non-mandatory, and one responder did not provide any answer, so answers were received from 97.3% (i.e. 36/37) of the total sample.

From Figure 13 it is evident that the two most rated recommendations, with a sum of agree and strongly agree of about 80% of the total respondents, are Develop research oriented harmonised European guidance on GDPR compliance in order to reduce divergence of interpretations and practice at national level, with the highest percentage of strongly agree (43%; 16/37) and Develop European training courses on GDPR compliance for researchers. It is worth noticing that only one respondent answers strongly disagree for each listed option and that this respondent was the same for all topics.

Figure 13



The remaining two options, Create a permanent expert group on GDPR compliance issues in health related EURATOM research (for example at Platforms coordination level) in order to elaborate proposals for improvement and Involve DPOs from an early stage of future European research projects development also got more than 50% of positive feedbacks (i.e. sum of agree and strongly agree) but received a higher number of undecided/neutral (35%, 13/37 and 29%, 11/37, respectively).

From the analysis of questions 20-23 it comes out that researchers are generally more favourable in improving their own knowledge and expertise in GDPR compliance issues than receiving support or advice from DPOs and expert groups, though the difference in approval of the listed options, translated in absolute numbers appear to be non-significant (30 respondents for the two best rated options versus 19 for the two least rated).

References

1. European Society of Radiology. ESR paper on structured reporting in radiology. Insights into Imaging. 2018;9(1):1-7.

2. Willemink MJ, Koszek WA, Hardell C, et al. Preparing Medical Imaging Data for Machine Learning. Radiology. 2020; 295(1):4-15.

3. Bockhold S, Foley SJ, Rainford LA, Corridori R, Eberstein A, Hoeschen C, Konijnenberg MW, Molyneux-Hodgson S, Paulo G, Santos J, McNulty JP. Exploring the translational challenge for medical applications of ionising radiation and corresponding radiation protection research. 2021 [submitted for publication]

4. Sudlow C, Gallacher J, Allen N, et al. UK Biobank: An Open Access Resource for Identifying the Causes of a Wide Range of Complex Diseases of Middle and Old Age. PLoS Medicine. 2015; 12(3):e1001779-e.

5. Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation).

6. European Commission. European Health Data Space [online]; 2022. Available from: https://ec.europa.eu/health/ehealth/dataspace_en.

7. Hansen J, Wilson P, Verhoeven E, et al. (on behalf of the EUHealthSupport consortium). Assessment of the EU Member States' rules on health data in the light of GDPR Specific Contract No SC 2019 70 02 in the context of the Single Framework Contract Chafea/2018/Health/03. EUROPEAN COMMISSION Consumers, Health, Agriculture and Food Executive Agency Unit: Health Unit.

8. European Commission, Directorate General for Energy, Jaschke W, Clark J, Hierath M, et al. European study on clinical diagnostic reference levels for X-ray medical imaging: EUCLID. Publications Office; 2021. Available from: doi/10.2833/031357

9. Jungmann F, Arnhold G, Kämpgen B, et al. A Hybrid Reporting Platform for Extended RadLex Coding Combining Structured Reporting Templates and Natural Language Processing. Journal of Digital Imaging. 2020; 33(4):1026-33.

10. Spaltenstein JC, Roduit N, van Dooren N, et al. Design of an Image and Radiation Dose Biobank (IRDBB) as a support for research on low dose radiation exposure in medical imaging. Poster presented at: European Society of Radiology EuroSafe Imaging EPOS Poster Exhibition; 15-19 July, 2020 [online].

Annex 2

Supporting evidence resulting from the stakeholder consultation process.

MEDIRAD stakeholder forum outcomes.

At the onset of the MEDIRAD project a stakeholder forum (SF) was established as a means of engaging in meaningful dialogue with a multidisciplinary group of representatives from the field of medical ionising radiation and associated protection research. The SF was consulted via a comprehensive questionnaire which aimed at ranking various broad-ranging approaches for optimisation of exposure to ionising radiation of patients and medical professionals and prioritise technical topics for inclusion in the current MEDIRAD recommendations.

Of the 86 SF members, there were 85 respondents to the questionnaire offering an interdisciplinary perspective from 69 nationals within Europe and 16 international representatives.

MEDIRAD stakeholder forum expectations.

Table 1
EUROPEAN STAKEHOLDERS' EXPECTATIONS: HIGH PRIORITY TECHNICAL TOPICS

Rank	Topics
1	Optimising image quality / dose during CT scans, including multimodality imaging procedures (e.g. SPECT-CT and PET-CT-scans).
2	Improved protocols aimed at reducing exposure whilst preserving or improving diagnostic quality/ therapeutic benefits (e.g. better accounting of potential secondary or late effects of healthy tissue exposure).
3	Optimising patient follow-up care after radiation therapy and collecting valuable epidemiological data through a better linkage of medical professionals from relevant disciplines.
4	Increasing education and training of medical professionals on radiation protection optimisation.

Table 2
EUROPEAN STAKEHOLDERS' EXPECTATIONS: INTERMEDIATE PRIORITY TECHNICAL TOPICS

Rank	Topics
5	Promoting individualised patient care in nuclear medicine. Procedure for evaluating patient-specific doses deliver to volumes and organs through activity uptake.
6	Improvement of target definition by better delineation of the target volume, better margins definition and better definition of the heterogeneity and of the biological volumes of the tumour at the voxel scale.
7	Modelling of patient dosimetry at the voxel scale. It is necessary to move from planned dose maps to delivered dose maps. (Treatment planning improvement, doses delivered during diagnostic and positioning imaging procedures, modelling simulations, clinical Decision Support System, Data standardisation and machine learning data base...).
8	Predicting quickly and accurately the response of tumours and normal tissues to ionising radiation using new multimodal and functional imaging and/or new biological and molecular surrogates. The development and validation of novel biomarkers will be required in order to develop treatment personalisation approaches.
9	Development of European registries of patient dose/imaging with recommended appropriate quantities (effective dose, organ dose) for radiological examinations.
10	Developing and validating operational biomarkers predictive of patient exposure – side or late adverse effects - following repeated radiological examinations, or radiotherapy protocols.
11	Optimising medical staff protection during interventional radiological procedures by ensuring proper availability and use of shielding equipment, while at the same time considering their actual effectiveness and efficacy.

Table 3
EUROPEAN STAKEHOLDERS' EXPECTATIONS: LOW PRIORITY TECHNICAL TOPICS

Rank	Topics
12	Technology development.
13	Future radiation protection research for radiation-oncology: Normal tissue response.
14	Development of European patient registries of dose/image/clinical diagnosis and patient follow-up, for the purpose of clinical procedure standardisation and radiation protection optimisation (European radio-vigilance).
15	Future radiation protection research for radiation-oncology: Combined treatment.
16	Modelling of patient dosimetry on an individual basis by highlighting the range of absorbed doses delivered from fixed administrations of activity, in order to evaluate the range of possible secondary effects, including long-term risks of secondary malignancies.
17	Future radiation protection research for radiation-oncology: Medical countermeasure.

Table 4
EUROPEAN STAKEHOLDERS' EXPECTATIONS: LOW INTEREST TECHNICAL TOPICS

Rank	Topics
18	Facilitating the development of large-scale multinational epidemiological studies by proposing guidelines to help European countries to implement at the national level European regulatory requirements on ethics (including compliance with GDPR directive).
19	Development of personalised protocols that factor in individual patient radiation sensitivity (e.g. via biomarkers of radiation sensitivity).
20	Exploring of the potential of patient-specific radiobiology tests to assess individual radio-sensitivity, in order to personalise treatment protocols.
21	Protocols to set up optimised imaging systems for quantitative imaging of I-131 irrespective of camera make or model.
22	Outlining a plan for a large-scale and multi-site epidemiological study to evaluate the effects of low absorbed doses of radiation as a result of nuclear medicine imaging procedures in a population with an expected normal life expectancy.
23	Consideration of individual bio-kinetics in patients with residual thyroid tissue or adjuvant disease, rather than reliance on models and values established for a healthy population.
24	Reinforcing regulations (e.g. by extending the scope of Diagnostic Reference Levels (DRLs) at the European level), and regulatory oversight (e.g. radiation protection experts, inspections).
25	Web/smartphone application for adverse effects.

For more information on the stakeholder consultation process and outcomes, see: M. Benderitter, E. Herrera Reyes, M.A. Benadjaoud, F. Vanhavere, N. Impens, U. Mayerhofer-Sebera, M. Hierath, J.R. Jourdain, G. Frija and J. Repussard. MEDIRAD formulation of science-based recommendations for medical radiation protection: a stakeholder forum survey. Radioprotection. 2021. 56(4), 275–285. doi: 10.1051/radiopro/2021030.

Annex 3

Stakeholder involvement in the development and implementation of Recommendations.

MEDIRAD Recommendations were elaborated on the basis of scientific findings from the research developed during the project, in consultation with stakeholder organisations which were invited to take part in the MEDIRAD Stakeholder Forum. This consultation process included an enquiry, based on on-line questionnaires aiming to identify priority concerns among stakeholder organisations, in the field of MEDIRAD scientific investigations, and a review of draft recommendations which were presented on-line to Forum members, and discussed at two workshops organised by MEDIRAD.

The list of MEDIRAD Stakeholder Forum members is provided hereafter. The publication of this list does not imply that the contents of MEDIRAD Recommendations are formally endorsed by these organisations. MEDIRAD Stakeholder organisations are invited to contribute to the dissemination and implementation of Recommendations or parts thereof, as they see fit within the limits of their missions and attributions.

MEDIRAD Stakeholder Forum Members, in alphabetical order:

· Associação Portuguesa dos Técnicos de Radiologia, Radioterapia e Medicina Nuclear
· Associazione Italiana di Radioprotezione Medica
· Associazione Italiana di Radioterapia Oncologica
· Associazione Italiana Medicina Nucleare
· Belgian SocieTy for Radiotherapy & Oncology
· Belgian Society of Radiology
· Biobank of Eastern Finland and University of Eastern Finland
· Bulgarian Society of Biomedical Physics and Engineering
· Bundesamt für Strahlenschutz (Federal Office for Radiation Protection)
· Cardiovascular and Interventional Radiological Society of Europe
· Commissariat à l'Energie Atomique et aux Energies Renouvelables
· Croatian Society of Radiology
· Czech Association of Medical Physicists
· Danish Health Authority, Radiation Protection
· Danish Society for Medical Physics
· Deutsche Gesellschaft für Biologische Strahlenforschung
· EFRS Educational Wing
· ESR EuroSafe Imaging
· ESR Patient Advisory Group
· European Network for Training and Education of Medical Physics Experts
· European Nuclear Education Network Association
· European Nuclear Education Network Association +project
· European Organisation for Research and Treatment of Cancer
· European Society for Vascular Surgery

· European Society of Medical Imaging Informatics
· European Society of Paediatric Radiology
· Federal Agency of Nuclear Control
· Federazione nazionale Ordini dei Tecnici di radiologia e delle professioni sanitarie tecniche, della riabilitazione e della prevenzione
· Finnish Advisory Committee for clinical audit
· Food and Drug Organization
· German Commission on Radiological Protection
· German Roentgen Society
· Greek Atomic Energy Commission
· Heads of the European Radiological Protection Competent Authorities
· Hellenic Society of Gastroenterology
· Hungarian Society for Medical Physics
· Institut National du Cancer
· International Agency for Research on Cancer, Section of Environment and Radiation
· International Atomic Energy Agency - Radiation Protection of Patients Unit
· International Commission on Radiological Protection
· International Organization for Medical Physics
· International Radiation Protection Association
· International Society of Radiographers and Radiological Technologists
· International Society of Radiology
· Irish Institute of Radiography and Radiation Therapy
· Irridium Network
· Istituto Nazionale per l'Assicurazione contro gli Infortuni sul Lavoro the National Institute for Insurance against Accidents at Work
· Italian Association for radiation Protection
· Italian Association of Medical Physics
· Kuopio University Hospital, Cancer Centre
· Lithuanian Association of Medical Physics and Engineering
· National Professional Association of Italian Qualified Experts
· Nordic Association of clinical Physics
· Nordic Working Group on Medical Applications
· Österreichische Röntgengesellschaft (Austrian Soicety of Radiation Protection)
· Plataforma Nacional de I+D en Protección Radiológica
· Quality Assurance Group in Radiotherapy
· Radiation Protection Association of Serbia and Montenegro
· Radiation Protection Officers working group on the West Coast of Norway
· Radiotherapy Translational and Preclinical Research network
· Romanian College of Medical Physicists
· Sociedad Española de Oncologia Radioterapica
· Società Italiana di Cardiologia
· Società Italiana di Cardiologia pediatrica e di cardiopatie congenite
· Società Italiana per la Radiologia Medica
· Societatea Română de Medicină Nucleară și Imagistică
· Société Française de Physique Médicale
· Société Française de Radiologie
· Société Française de Radiothérapie Onocologie
· Society and College of Radiographers
· St. James's University Hospital
· Superior Health Council
· Swedish Society for Medical Physics
· Swedish Society of Medicine
· Swiss Society of Radiobiology and Medical Physics
· University Hospital Leuven
· University of Arkansas
· University of California
· University of Eastern Finland
· University of Ghent
· University of Malta
· WHO network of Patients for Patient Safety

Annex 4

The MEDIRAD Project

Implications of Medical Low Dose Radiation Exposure.

A European multi-disciplinary project to enhance the scientific bases and practice of radiation protection in the medical field.

Coordinator	**European Institute for Biomedical Imaging Research (EIBIR), AT** **Coordinator contact: Monika Hierath, mhierath@eibir.org**
Scientific Coordination	**Prof. Elisabeth Cardis** **Barcelona Institute for Global Health (ISGlobal), ES**
Clinical Coordination	**Prof. Guy Frija** **Paris Descartes University, FR**
Duration	**1 June 2017 – 28 February 2022 (57 months)**
Total max EU Funding	**€9,995,145.75**
Website	**www.medirad-project.eu**

Ambition

MEDIRAD is a multi-disciplinary, cross-cutting project that aims to enhance the scientific bases and clinical practice of radiation protection in the medical field. MEDIRAD addresses the need to better understand and evaluate the health effects of low-dose ionising radiation exposure from diagnostic and therapeutic imaging and from off-target effects in radiotherapy. The MEDIRAD key research objectives are summarised in three pillars:

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

Work plan

The MEDIRAD Project consisted of six interdependent and complimentary work packages (WP).

- **WP1:** Project management and dissemination: Scientific and clinical coordination, ethics management, knowledge management and exploitation, internal and external communication.
- **WP2:** Dose evaluation and optimisation in medical imaging: Optimisation of chest CT, interventional procedures and multimodality imaging, and development of imaging and radiation dose biobank.
- **WP3:** Impact of low-dose radiation exposure: Standardisation, biokinetic modelling and treatment planning, dosimetry, biomarkers of absorbed doses, protocol for epidemiological study.
- **WP4:** Breast radiotherapy and secondary cardiovascular risks: Epidemiological study on cardiovascular changes after radiotherapy, measuring markers of exposure and risk modelling.
- **WP5:** Possible health impact of paediatric scanning: Epidemiological study of paediatric CTs and cancer, including (epi)genetic biomarkers of possible sensitivity, dosimetry and statistical analyses.
- **WP6:** Bringing together medical & nuclear scientific communities: Formulation of science-based policy recommendations, consultation of stakeholders, organisation of dissemination seminars.

Impact

MEDIRAD will achieve significant progress in the interaction between the radiation protection and medical scientific communities at EU level, leading to cross-fertilisation of research efforts and the provision of more consolidated and robust science-based policy recommendations to decision makers in the respective sectors.

MEDIRAD will allow a better evaluation of the risks from radiation and better quantification of the necessary precautionary measures, leading to a more robust system of protection of patients, workers and the general public, whilst not unduly penalising activities through unnecessary and costly measures.

MEDIRAD will endeavor to positively modify the public perception of risks associated with ionising radiation thanks to the results of such combined nuclear and medical research.

MEDIRAD's long-term impacts are additional and improved practical measures for the effective protection of people in the medical and nuclear sectors.

Consortium

The multi-disciplinary consortium combines the expertise of 34 partners from 14 European countries. It includes major universities and research institutes as well as clinical partners.

· European Institute for Biomedical Imaging Research, AT
· Belgian Nuclear Research Centre, BE
· Ghent University, BE
· University of Geneva, CH
· Otto von Guericke University Magdeburg, DE
· University Medical Center of the Johannes Gutenberg University Mainz, DE
· Helmholtz Zentrum München German Research Center for Environmental Health, DE
· University Hospital of Würzburg, DE
· Philipps University of Marburg, DE
· University Hospital rechts der Isar of the Technical University Munich, DE
· Brandenburg Medical School, DE
· Barcelona Institute for Global Health, ES
· Polytechnic University of Catalonia, ES
· Autonomous University of Barcelona, ES
· Catalan Institute of Oncology, ES
· Paris Descartes University, FR
· Institute for Radiological Protection and Nuclear Safety, FR
· B-COM, FR
· French National Institute of Health and Medical Research FR
· Claudius Regaud Institute FR
· University of Crete GR
· University College Dublin, National University of Ireland, IE
· Sapienza University of Rome, IT
· Italian National Institute of Health, IT
· University Medical Center Groningen, NL
· VU University Medical Center, NL
· Netherlands Cancer Institute, NL
· Nofer Institute of Occupational Medicine, PL
· Polytechnic Institute of Coimbra, PT
· Cardiovascular Centre of the University of Lisbon, PT
· Region Västra Götaland, SE
· The Royal Marsden National Health Service Trust, UK
· University of Newcastle upon Tyne ,UK
· Imperial College London, UK

This project has received funding from the Euratom research and training programme 2014–2018 under grant agreement No 755523.