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D4.2 SWOT for establishment of centre(s) of excellence in medical application of ionising radiation

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Tables of contents

Abbreviations

CoE	Centre of excellence
D4.1	Deliverable 4.1
IR	ionising radiation
MS14	Milestone 14
QALYS	Quality adjusted life years
RP	Radiation protection

Disclaimer

The opinions stated in this report reflect the opinions of the authors and not the opinion of the European Commission.

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1. Introduction

One aim of the EURAMED rocc-n-roll project is to investigate the question whether and how in the future, research on medical applications of ionizing radiation as well as the corresponding radiation protection issues can benefit from European infrastructures[1, 2, 3]. This includes elaborating on the potential benefits but also potential risks of often proposed centre(s) of excellence (CoEs). For all of such evaluations the final goal of a better, more efficient and safe care of patients throughout Europe has to be taken into account.

As it has been described in EURAMED rocc-n-roll deliverable 4.1 (D4.1)[4] there are various options for defining CoEs, depending on the objectives and expected impacts, and thus there are also corresponding options that how the evaluations can be properly done. These various options have been derived and have been described in D4.1. As a guidance/suggestion for how to foster realisation of the research priorities recommended by the EURAMED rocc-n-roll SRA, as well as to increase the benefit for European patients, a series of 22 criteria were derived from D 4.1, a survey on CoEs and external expert discussions. These criteria are reported and described in detail in EURAMED rocc-n-roll milestone MS14. It should be mentioned already at this point, that the criteria derived already depend on some basic assumptions. Task 4.1 of the EURAMED rocc-n-roll project tried to take into account approaches for centres of excellence as often used in the context of radiation protection research, but also to combine this with approaches which can be described as clinical centres of excellence. It should be noted that as visible in the previously performed literature research the concepts are often very different. Nevertheless, the options derived in D4.1 seem to cover the different approaches and the task members tried to combine in some options at least the aspects of both concepts for the best sake of the patients.

The goal of the current deliverable is to describe how the various options are evaluated with respect to the above-mentioned task of the EURAMED rocc-n-roll project. A SWOT analysis is conducted for this purpose. The SWOT analysis is based on the criteria elaborated as documented in MS14 and in brief summarised in chapter 3 of this deliverable.

It should be clearly stated already at this point that the most suitable option does not need to fulfil all criteria. And it also does not exclude other options which might be chosen for practical, political or other reasons. Certainly, the proposed method and the corresponding results do not mean that there could not be other forms of assessment of such options.

2. Methodology

Through a series of online and onsite meetings with panel members and external experts, as well as literature review, 6 options of CoE(s) have been identified and described. In parallel, a CoE survey had been conducted online for a few months. In this survey, participants were asked about their opinion what CoE(s) would be needed, what would be expected from such centres and what would be criteria for such centres in the context of medical applications of ionizing radiation and the corresponding radiation protection issues, considering the current research and medical care situation from their point of view.

Using the results of this survey and the meetings of the experts as well as the meeting of the EURAMED rocc-n-roll project in Freising in June 2022, where the survey and its preliminary results have been presented, the task 4.1 of the project put together a list of criteria. This is described in milestone MS14. The list has been just derived from the input from the survey and the experts' opinions, no additional criteria had been added. The criteria had been grouped, nevertheless. This list of criteria is in this document then used to address which of the criteria would be fulfilled (strengths), would not be fulfilled (weaknesses), could be achieved or

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implemented well with corresponding benefit (opportunities) or cannot be (easily) implemented and might have a negative impact on the potential research tasks as to be defined in the research agenda.

Finally, a conclusion is drawn, using this SWOT analysis to propose a suitable option for a CoE structure in the context of medical applications of ionizing radiation and the corresponding radiation protection in terms of European research achievements and in terms of harmonised patient benefit throughout Europe.

It needs to be clearly stated here, that for sure, it will nearly be impossible for one single type of CoE structure to fulfil all criteria and this is also not mandatory to build up an optimal CoE structure. This is due to various reasons: First of all, as mentioned, it will hardly be possible to fulfil all criteria especially as some criteria are more focused on disease treatment, while others are more focused on research aspects. Secondly, criteria are in the milestone currently just listed and ordered according to aspects but not ranked in terms of importance. This has been avoided as it might be very subjective. There is also a third aspect, which is that criteria might not be fulfilled from the beginning, but the structure has the potential to do so. The fourth argument is that some criteria might be covered by existing structures. With respect to this, it is necessary to be clearly stated that the final decision on suitable options should not be taken just by numbering out the number of criteria listed in strengths and opportunities on the one hand side and weaknesses and threats on the other hand.

In summary, the SWOT analysis is a way forward to compare the different options and generate a basis for the proposed approach for future research optimisation in the field of medical applications and corresponding radiation protection for the best sake of patients throughout Europe.

3. Criteria for Centre(s) of Excellence

The EURAMED rocc-n-roll SRA, which is under development, presents recommendations of research priorities in the field of medical IR and relevant RP from the rocc-n-roll consortium and a broad range of stakeholders. As a guidance/suggestion for how to foster realisation of these research priorities in order to increase the benefit for European patients, a series of 22 criteria for CoEs were derived from Deliverable 4.1 "*Options for centre(s) of excellence for medical application of ionising radiation and medical radiation protection research*", the CoE survey and external expert discussions.

The criteria could be classified and in a certain way ranked considering the results of the survey. However, ranking the criteria is not the goal in this document, considering that the survey participants and experts have differing knowledge, understanding and interests of a CoE, based on their own profiles. Moreover, for different CoE options, the priority and importance of each criterion could differ. In addition, the distribution of the participants across disciplines and profiles, which would influence the individual interest and understanding of an CoE, was not totally even. Thus, the ranking might not help to implement a consensus approach. Without intending to rank, the votes from the survey are nevertheless reflected as: **Survey high interest (SHI)**", "**survey median interest (SMI)**", "**survey low interest (SLI)**" Only part of the criteria have such identification, because the rest were derived from D4.1 and expert inputs.

The intention of proposing this set of criteria and the future SWOT analysis is not to directly measure and treat the existing CoEs as definitive results, but rather, to provide a tool for the (potential) CoEs to use it for a self-orientation and a corresponding evaluation, in order to support further development and improvement of those centres in achieving their goals and

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interests. To guide the self-development of potential CoEs in a more comprehensive way instead of only focusing on one direction, these criteria are organised into 3 categories:

I. Activity (i.e., constitution)

II. Objective (i.e., practice)

III. Impact

The criteria are listed in no particular order.

In order to increase the future impact, it is strongly recommended that the potential CoE(s) progresses in all three categories, instead of only specialise on one category.

Furthermore, the criteria are intended to be used to perform the SWOT analysis for the options provided in EURAMED rocc-n-roll D4.1.

I. Activity

1. Open access data repository (SHI)

A data repository is in this context defined as a collection of data sets which allows to share data across European borders and institutions with a common strategy, common rules, standardisation, and a coordination in resources to ensure safe and trustworthy accessibility and management of data including GDPR regulations. It might also contribute to improving patient care through personalised medicine potential via an interlink between the relevant data and a corresponding biobank.

2. Biobank

A biobank collects, administrates and stores biological samples (usually human) for (multiple) research purpose. Biobanks provide researchers access to data representing a large number of people, based on the donor's consent and the Biobank Act. Easy access to a biobank data is ideally coupled to quality assured imaging data and therapy follow up data is important for future research in whole Europe.

3. Interdisciplinarity (SMP)

It is necessary to foster interdisciplinary approaches in the field of medical applications of IR and the corresponding RP as both fields rely on the involvement of various expertise including both basic research and clinical research.

4. Management strategy and leadership

The CoE organization shall have a common strategy and objectives Such processes need to include planning methods and evaluation tools.

5. National self-declaration, external-recognition/ national or international-certification, accreditation

Clinical care needs to be agreed and approved. The basic research behind it must be included as well as a guaranteed optimised care and an evidence-based approach for personalised patient care. This might be stated by self-declaration, or external recognition/ national or international certification, or even accreditation.

The 3 levels of proof offer and encourage each candidate to pursue a volunteer approach, to develop and decide by its own to reach which level.

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6. Open access technology/ equipment (SMI)

A CoE should organise the possibility to use its potentially high-level technology, equipment, research infrastructure and relevant expertise for patient care applications and for researchers working on related topics. Duplication of efforts should be avoided.

II. Objective

7. Translational research to care

The organization of the translational activity from research to applications for care “from bench to bedside” as quickly as possible is the major goal of research on medical applications of ionizing radiation and radiation protection as to improve the patient benefit (or/and reduce risks) on a personal patient perspective throughout Europe.

8. High standards of care and leadership (SHI)

High quality clinical service including a comprehensive clinical set of treatment options and quality care, with sufficient possibilities of different services and variants in technology are important for improving personalised health care, thus they are also necessary criteria for a CoE structure.

9. Clinical research

Clinical research should be included in the activities of a CoE structure. An environment is needed to enable clinical researchers to focus mainly on improving diagnostic and or treatment protocols, programs, and outcomes for patients; The scientific research needs to be driven by medical needs and thus must allow and foster the inclusion of clinical researchers and clinicians also from outside of the CoE structure. The final goal needs to be improved health care for patients and thus the translation of the results.

10. Integrating innovation (SLI)

CoE should be able to efficiently integrate innovation developed outside of the CoE structure into its own practice.

11. Transferring innovation (SLI)

A CoE structure needs to have methods to identify and acknowledge innovations. The developed innovation within an CoE should be translated into clinical care and transferred into industry.

12. Integrated practice unit (IPU)

An IPU is defined as a unit that is “organised around the patient and providing the full cycle of care for a medical condition, including patient education, engagement and follow up and encompass in-patient, out-patient and rehabilitative care as well as supporting services.” Such an IPU is relevant for medical applications, in terms of efficient exchange during clinical needs driven research.

13. Integrated healthcare delivery model

“Integrated health services delivery is defined as an approach to strengthen people-cantered health systems through the promotion of the comprehensive delivery of quality services across

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the life-course, designed according to the multidimensional needs of the population and the individual and delivered by a coordinated multidisciplinary team of providers working across settings and levels of care. It should be effectively managed to ensure optimal outcomes and the appropriate use of resources based on the best available evidence, with feedback loops to continuously improve performance and to tackle upstream causes of ill health and to promote well-being through intersectoral and multisectoral actions."

---- by WHO Regional Office for Europe

A CoE for research should foster such integrated health services delivery and should therefore take such standards into account including a European wide approach.

14. Network of researchers beyond the CoE (SHI)

The CoE structure should foster a networking and a corresponding basis for collaborations as well as the potential to further develop the network and establish such a basis along the lines of interdisciplinary as described above.

15. Personalised medicine - individual patient care, patient-centric view

Personalised medicine or precision medicine, describes the tailoring of medical decisions, procedures, practices, interventions and/or products to the individual patient based on their predicted response or risk of disease. The patient-cantered approach and the personalised medical approach, needs to be a central aspect of the CoE structure in the context of medical applications of IR.

16. Knowledge of diseases including the associated biology and fundamental mechanisms of disease

Improving the individual patient care for all European patients must be the main research driver for medical application of IR. Thus, a CoE structure needs to be able to provide up-to-date insights of biology of many of the disorders and diseases, and the corresponding pathology, as well as diagnose and treatment of the relevant diseases in clinical settings.

III. Impact

17. Impact on society

A CoE structure needs to gain societal impact in terms of desired results of multiple strategically designed funding and intervention efforts to improve the well-being of all members of the society by means of the research and clinical care.

18. European impact

The potential to acquire benefit for the entire European population as a whole is a mandatory aspect of research regarding especially personalised medicine approaches making use of ionizing radiation.

19. Education and training (SMI)

For a European CoE that is meant to benefit the whole population by fostering and enabling research allowing equality and sustainability, one obvious mission is the training of the current as well as the future researchers and medical doctors in the field including the development of feasible concepts.

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20. Dissemination connected to learning

For translating the achieved outcomes of a CoE structures, its researchers need to collaborate with hospitals to have a continuous exchange on clinical needs and to help the hospitals to improve procedures and protocols, including disseminating the latest and best practice and innovation to all hospitals outside of the CoE structure.

21. Economic impact, Sustainability of technologies including imaging technologies and medical care products

A CoE structure should help to generate sustainable provision of research technology, medical care technology as well as medical care products. It should also be able to evaluate needs in terms of clinical procedures and for the potential transfer into industry. Development and dissemination of novel clinical procedures throughout Europe, and the consequent improvement in health of the population to increase the number of QALYS. These all together also have significant overall economic impact on the workforce.

22. Structuring the European health care support systems

CoE experts should provide recommendations to develop European health care support systems through for example participating in international activities like WHO, IAEA, OECD et al., to establish regulatory standards for health care applications based on ionizing radiation.

4. Results of SWOT analysis

We show the SWOT analysis results for every single option as outlined in D4.1. For this it should be clearly stated that not all criteria mentioned in milestone MS14 can be elaborated for each option as it might depend on the way of implementation and how thinks are developing.

Option 1): No dedicated CoE but only networks between existing technology based or disease related national system of identification.

Strengths

For this option, the following criteria are assumed to be fulfilled and can thus be considered as strengths:

- **Open access data repository** is available in some institutions of the networks or in technology or disease-centres.
- **High quality and up-to-date high standards of care and leadership** can be provided in national disease related excellence centres.
- **High quality and up-to-date clinical research** will for sure be possible.
- **Interdisciplinarity** is given in many centres and can be enforced in the network. Nevertheless, this depends on the included centres.
- **Innovation** in terms of generating innovation is assumed to be possible in such a network, through an active exchange and dynamic collaboration. Although, it might be limited as all partners might aim for different aspects. This might be even more complex for integrating innovations from outside within the whole network.
- **Knowledge of diseases including the associated biology and fundamental mechanisms of disease** shall be available in the disease related centres but typically specific for certain diseases only and sometimes limited to parts of the system.
- **Interaction of researchers** will be a key asset of such a network as researchers are typically directly involved in the setting up of that network and are thus committed, which is a good base for **network of researchers beyond the CoE**.

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Weaknesses

In case there are relevant limits in fulfilling the criteria or a complete failing on a criterion, this is listed here as a weakness:

- **No single biobank** will be available as different data will be stored in the different hubs of such networks most probably and data transfer might be difficult.
- **Not so much translational research to care** can be expected to be dealt with as the most existing clinical centres are focused on certain diseases and most technical centres are driven by their technological expertise.
- **Localised clinical care service** will be a major aspect as high-quality clinical care will especially be provided in a few national dedicated clinical health care centres. Since it is not easy to transport patients and medical resources across borders, this will limit the service to be available everywhere.
- A network will not be committed to set up common structures resulting in a **lack of an integrated practice unit and an integrated healthcare delivery model.**
- There will **not** be **an efficient management strategy and leadership** easily implemented. Thus, the structure needs to have a common strategy including processes of evaluation, planning, and implementation.
- It might be **challenging to share open access technology/ equipment** as there is no legal entity.
- As the network will only be a loose connection, major aspects of standardization for **personalised medicine approaches will be difficult** to set up.
- In a same way, due to a lack of given contractual aspects, it will be **challenging to share staff and expertise** including IT expertise, which means that the knowledge is provided by a team of expertise that are highly specialised and being well managed, so to achieve sustainable expertise.

Opportunities

As opportunities, we define criteria that are not necessarily easy to fulfil in the option to be evaluated or such aspects/ criteria which will allow dedicated positive developments:

- As the network structure is very open and not limited it will easily be **possible to build further networks for more translational research to cares** once they seem to be needed.
- As a network is not bound by fixed regularities this might allow an outreach into the public and an easier distribution of results to industrial partners, which that allowing potentially an **increase of the impact on society, also on a European level and market prominence**
- As networks are flexible tools, they could help enhancing a network of researchers to **bring together a European approach and generate impact for the researchers and the population**
- In a similar way**, international impact can be increased.**

Threats

Criteria, that are potentially difficult to be fulfilled or cannot be fulfilled and that might hamper the improvement of useful research on medical applications of ionizing radiation in medicine

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or the corresponding radiation protection for the individualised patient benefit throughout Europe are listed in this category:

- **Data format** for the data in the different **biobanks** as well as the **open data and imaging repositories might not be congruent** between all centers and as there are no legally binding structures this might be deteriorating the common overarching use of such data.
- As networks will build themselves without influence from outside and typically between national disease or technology centres, the research will be driven by their interests rather than by the interests of the patients in general and without the broader community of clinical care, thus potentially **excluding clinical researchers in hospitals/ clinical research outside of the network**
- Due to the lack of legal structure, it is potentially **difficult to implement (Inter-)national labelisation/ certification/accreditation**
- It will be difficult to predict whether such a network can help to build up and **guarantee sustainable resources efficiently** or to **structure the European Health Care Support system** as well as the required **education and training structure**. This does not mean it is not possible, but there are potential problems and weaknesses.

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In summary:

Option 1: No dedicated CoE but only networks between existing technology based or disease related national system of identification.

Strengths	**Weaknesses**
- Open access data repository is available; - High quality and up-to-date high standards of care and leadership can be provided; - High quality and up-to-date clinical research will for sure be possible; - Interdisciplinarity is given and can be enforced in the network; - Innovation in terms of generating innovation is assumed to be possible through an active exchange and dynamic collaboration; - Knowledge of diseases including the associated biology and fundamental mechanisms of disease shall be available; - Network of researchers beyond the CoE is feasible.	- No single biobank; - Not so much translational research to care; - Localised clinical care service; - Lack of an integrated practice unit and an integrated health delivery model; - Implementation of an efficient management strategy and leadership would be challenging; - It might be challenging to share open access technology/ equipment as there is no legal entity; - Major aspects of standardization for personalised medicine approaches will be difficult to set up; - In a same way, due to a lack of given contractual aspects, it will be challenging to share staff and expertise including IT expertise.
Opportunities	**Threats**
- Possible to build further networks for more translational research to cares; - Increase of the impact to the community and market prominence; - Bring together a European approach and generate impact for the researchers and the population; - International impact can be increased;	- Data format might not be congruent among different biobanks; - Excluding clinical researchers, hospitals outside of the network potentially; - Difficulties to implement (Inter-)national labelisation/ certification; - It will be difficult to predict whether such a network can help to build up and guarantee sustainable resources efficiently or to structure the European Health Care Support system as well as the required education and training structure.

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Option 2): A unique CoE as described above localised in one country that cover all the requirements to develop research activities reported in the EURAMED rocc-n-roll SRA.

Strengths

For this option, we assume that the following criteria are fulfilled and can thus be assumed as strengths of this option:

- It can be assumed that such a unique CoE can provide efficient management of an **open access data repository** as well as a high productivity because of more shared common research interests and concentrated expertise. However, it might be limited to the national researchers of the CoE location.
- This might include a suitable management and easy access to a **biobank**, due to an overlapping research focus and e.g. easy gathering and transportation/storage of bio-samples.
- A unique CoE shall have a **management strategy and leadership**.
- (Inter-)national labelisation/ certification/accreditation would be feasible, but **international labelisation/ certification** might be difficult due to heterogeneous situations across countries.
- **Open access technology/ equipment** would be available if the CoE allows it and is equipped accordingly. This would be feasible in terms of sharing and implementing funding, management, maintenance as well as close collaboration, but could enable researchers of the hosting nation more efficient than others.
- Within a localised centre, it is convenient to establish and maintain an active **network of researchers**, at least within the centre.
- Such a CoE will most probably have a localised and rather national wise **impact on society, not a European one**.
- **Excellent research** can be fostered by and performed in such an integrative centre using the guidance of the EURAMED rocc-n-roll SRA.
- **Knowledge of diseases including the associated biology and fundamental mechanisms of disease** might be given depending on the setup scenario of the centre as it is rather technically oriented.

Weaknesses

In case there are relevant limits in fulfilling the criteria or a complete failing on a criterion this is listed here as a weakness:

- It will be most probably a research centre thus does not provide any **high standards of care and leadership, integrated practice unit**
- As a research-oriented centre, it does not necessarily provide direct medical care including **personalised medicine**.
- Not so much **translational research to care** will be performed.
- As the centre is not mainly attributed to medical care and is located in one country it would most probably not be ideal as an **integrated healthcare delivery model.**
- Such a centre will most probably not help to structure the **European Health Care support system.**
- It is not very likely, that one single centre can really help to **guarantee sustainability of technology and medical care products** for whole of Europe.

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Opportunities

As opportunities we define criteria which could be fulfilled but are not necessarily easy to fulfil in the option to be evaluated or such aspects which will allow dedicated positive developments based on some criteria:

- Such a centre can be covering in principle the full range of required **Interdisciplinarity**, but it is not given per se. It needs a lot of effort to construct the centre that way that especially clinical expertise, technological and biological expertise are all represented.
- Such a centre does not necessarily already have but has the good potential for **establishing links for innovation and transfer**, because it should be research driven by clinical needs that benefits patients. Especially the transfer into clinical European-wide use is however challenging if the centre is a national centre or even just nationally located taking into account the differences in clinical care throughout Europe currently existing.
- **Integrating innovations** from outside the centre is not necessarily given but should be feasible depending on the management and the strategy.
- It is certainly a valuable **Education and training** facility for researchers as well as students, which can be fostered via collaboration with universities and hospitals. Again, the challenge is the pure one-nation approach.

Threats

Criteria, that are potentially difficult to be fulfilled or cannot be fulfilled and that might hamper the improvement of useful research on medical applications of ionizing radiation in medicine or the corresponding radiation protection for the individualised patient benefit throughout Europe are listed in this category:

- As this option describes a centre in one location there is a big threat that the localised centre functions only national wise and thus certainly hampers a **European approach/ impact**, as well as the **international impact**. This might be true for many aspects like **excellence in research**, easy access to **data banks**, **high standards of care and leadership**, adjustment to different approaches in different European countries, **education and training**.

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In summary:

Option 2: A unique CoE as described above localised in one country that cover all the requirements to develop research activities reported in the EURAMED rocc-n-roll SRA,

Strengths	**Weaknesses**
- Efficient management of an open access data repository based on common research interests; - A suitable management and easy access to a biobank; - Management strategy and leadership; - (Inter-)national labelisation/ certification/accreditation would be feasible, but international labelisation/ certification might be difficult due to heterogeneous situations across countries; - Open access technology/ equipment would be feasible; - Network of researchers within the centre; - Rather national wise impact on society, not a European one; - Excellent research can be fostered; - Knowledge of diseases including the associated biology and fundamental mechanisms of disease.	- It will be most probably a research centre thus does not provide any high standards of care and leadership, integrated practice unit; - It does not necessarily provide direct medical care including personalised medicine; - Not so much translational research to care will be performed; - It would most probably not be ideal as an integrated healthcare delivery model, nor being helpful for structuring the European Health Care support system; - One single centre would be hardly helpful for guaranteeing sustainability of technology and medical care products for whole of Europe.
Opportunities	**Threats**
- With sufficient efforts, it can cover in principle the full range of required interdisciplinarity; - Good potential for establishing links for innovation and transfer; - With suitable management and strategy, integrating innovations from outside the centre is feasible; - It is certainly a valuable education and training facility; the challenge is the pure one-nation approach.	- A localised centre functions only national wise and thus certainly hampers a European approach/ impact; - Challenges in achieving excellence in research, easy access to data banks, high standards of care and leadership; - Challenges in adjustment to different approaches in different European countries, as well as in education and training.

Option 3): A unique disease-oriented CoEs as described above and in 2) in Europe (one per disease).

Strengths

For this option, we assume that the following criteria are fulfilled and can thus be assumed as strengths of this option:

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- It can be assumed that such a unique disease-oriented CoE can provide efficient management of an **open access data repository** as well as a high productivity because of more shared common research interests and concentrated expertise. However, it might be limited to the national researchers of the CoE location and there will be different repositories for different diseases.
- This might include a suitable management and easy access to one or more **biobanks**, due to an overlapping research focus and e.g. easy gathering and transportation/storage of bio-samples.
- A unique disease-oriented CoE shall have a **management strategy and leadership**.
- (Inter-)national labelisation/ certification/accreditation would be feasible, but **International labelisation/ certification/accreditation** might also in this case be difficult due to heterogeneous situations across countries.
- **Open access technology/ equipment** would be available if the CoE allows it and is equipped accordingly. Technological equipment might be focused on biological or medical technology. The access would be feasible in terms of sharing and implementing funding, management, maintenance as well as close collaboration, but could enable researchers of the hosting nation more efficient than others.
- Within a localised centre, it is convenient to establish and maintain an active **network of researchers**, at least within the centre.
- Such a CoE will most probably have a localised and rather national wise **impact on society** based in parts on potential **translational research for care**. The **impact** will most probably not be that strong on the **European level.**
- **Excellent research** including **clinical research** can be fostered by and performed in such an integrative centre using the guidance of the EURAMED rocc-n-roll SRA.
- **Knowledge of diseases including the associated biology and fundamental mechanisms of disease** will be given depending on the setup scenario of the centre as it is disease oriented.

Weaknesses

In case there are relevant limits in fulfilling the criteria or a complete failing on a criterion this is listed here as a weakness:

- The proposed structure will be most probably a research centre (one per disease), thus does not necessarily provide any **high standards of care and leadership, integrated practice unit**, nor **integrated healthcare delivery model,** however, the disease focus might help providing this for some of the diseases in question.
- It might be difficult to integrate **clinical research** across European hospitals.
- It is unclear whether a focus on **personalised medicine** can be achieved.
- There might be a potential limit in **open access technology/ equipment**.

Opportunities

As opportunities we define criteria which could be fulfilled but are not necessarily easy to fulfil in the option to be evaluated or such aspects which will allow dedicated positive developments based on some criteria:

- Such a disease-oriented centre can be covering in principle the full range of required **Interdisciplinarity**, but it is not given per se. It needs a lot of effort to construct the centre that way that especially clinical expertise, technological and biological expertise

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are all represented. And for the approach of disease oriented centres it needs specific efforts to include the technical expertise.

- Such a centre does not necessarily already have but has the good potential for **establishing links for innovation and transfer**, because it should be research driven by clinical needs that benefits patients. Especially the transfer into clinical European-wide use is however challenging if the centre is a national centre or even just nationally located taking into account the differences in clinical care throughout Europe currently existing.
- **Integrating innovations** from outside the centre is not necessarily given but should be feasible depending on the management and the strategy.
- It is certainly a valuable **Education and training** facility for researchers as well as students, which can be fostered via collaboration with universities and hospitals. Again, the challenge is the pure one-nation approach.
- It is not very likely, that one single centre can really help to **guarantee sustainability of technology and medical care products** for whole of Europe however, it could still be tried.

Threats

Criteria, that are potentially difficult to be fulfilled or cannot be fulfilled and that might hamper the improvement of useful research on medical applications of ionizing radiation in medicine or the corresponding radiation protection for the individualised patient benefit throughout Europe are listed in this category:

- As this option describes a centre in one location there is a big threat that the localised centre functions only national wise and thus certainly hampers a **European approach/ impact**, as well as the **international impact**. This might be true for many aspects like excellence in research, easy access to data banks, **high standards of care and leadership**, adjustment to different approaches in different European countries, education and training.
- Such a centre will most probably not help to structure the **European Health Care support systems, but only that one of the hosting country.**

This project has received funding from the Euratom research and training programme 2019-2020 under grant agreement No. 899995.

In summary:

Option 3: A unique disease-oriented CoEs as described above and in 2) in Europe (one per disease).

Strengths	**Weaknesses**
- Efficient management of an open access data repository; - A suitable management and easy access to a biobank due to overlapping research focus; - Management strategy and leadership - Feasible national labelisation/ certification/ accreditation, but it would be challenging to achieve international wise; - Open access technology/ equipment would be available if it is equipped accordingly, but can be more efficient for the hosting nation than for the others; - Active network of researchers, at least within the centre; - National wise impact on society; - Translational research to care; - Clinical research can be fostered using the guidance of the EURAMED rocc-n-roll SRA; - Knowledge of diseases including the associated biology and fundamental mechanisms of disease.	- As a research centre, it does not provide any high standards of care and leadership, nor integrated practice unit and integrated healthcare delivery model; - It might be difficult to integrate clinical research across European hospitals; - It is unclear whether a focus on personalised medicine can be achieved; - Potential limit in open access technology/ equipment
Opportunities	**Threats**
- It can cover in principle the full range of required Interdisciplinarity, with a lot of constructing efforts; - It has good potential for establishing links for transferring innovation; - Integrating innovations from outside the centre should be feasible depending on the management and the strategy; - It is certainly a valuable Education and training facility; - A guarantee of sustainability of technology and medical care products for the whole Europe is not likely, however, it could still be tried.	- The localised center might function only national wise and thus certainly hampers a European approach/ impact; - The localization might limit achieving excellence in research; - Challenges in easy access to data banks and high standards of care and leadership, and education and training.

This project has received funding from the Euratom research and training programme 2019-2020 under grant agreement No. 899995.

Option 4) A CoE as described in 2) but distributed throughout Europe; up to one per country, probably requiring high levels of buy-in from national governments.

Strengths

For this option, we assume that the following criteria are fulfilled and can thus be assumed as strengths of this option:

- It can be assumed that such a unique CoE can provide efficient management of an **open access data repository** as well as a high productivity because of more shared common research interests and expertise. However, it might be distributed over the different CoE locations and maybe separated and not standardised.
- This might include a suitable management and easy access to **biobanks in the centres**, due to an overlapping research focus and e.g. easy gathering and transportation/storage of bio-samples.
- Each CoE shall have a **management strategy and leadership**. It would be ideal if the strategies of the different centres in the various countries could be aligned.
- (Inter-)national labelisation/ certification/accreditation would be feasible, but (I**nter-) national labelisation/ certification/ accreditation** might be difficult due to heterogeneous situations across countries. However, one centre per country could be certified.
- **Open access technology/ equipment** would be available if the CoEs allow it and are equipped accordingly. This would be feasible in terms of sharing and implementing funding, management, maintenance as well as close collaboration, but differences between nations might be possible.
- Within each localised centre, it is convenient to establish and maintain an active **network of researchers**.
- Such CoEs will most probably have localised **impact on society,** which might sum up to a **European wide impact**.
- These CoEs can help to **guaranty sustainable access to technology** and partly to medical care products, while for the medical care products this would be unclear as the CoEs are not disease-driven.
- **Excellent research** can be fostered by and performed in such integrative centres using the guidance of the EURAMED rocc-n-roll SRA.
- **Knowledge of diseases including the associated biology and fundamental mechanisms of disease** might be given depending on the setup scenario of the centres as they are rather technically oriented.

Weaknesses

In case there are relevant limits in fulfilling the criteria or a complete failing on a criteria this is listed here as a weakness:

- It will be most probably technically driven research centres thus do not provide any **high standards of care, integrated practice unit**
- As the centre is not mainly attributed to medical care and is located in one country it would most probably not be ideal as an **integrated healthcare delivery model.**
- Not so much **translational research to care** will be performed**.**
- Such centres will most probably not help to structure the **European Health Care support system.**

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- As a research-oriented centre, it does not necessarily provide direct medical care including **personalised medicine**. Also, there might **not** be a strong tendency for **clinical research** and to **include hospitals throughout Europe** within the research approaches.
- As every nation will have its own centre it is most probable that **infrastructures as well as resources** will **be doubled.**
- There might be **competition between CoEs and no clear single contact for researchers**.

Opportunities

As opportunities we define criteria which could be fulfilled but are not necessarily easy to fulfil in the option to be evaluated or such aspects which will allow dedicated positive developments based on some criteria:

- Such centres can be covering in principle the full range of required **Interdisciplinarity**, but it is not given per se. It needs a lot of effort to construct the centres that way that especially clinical expertise, technological and biological expertise are all represented.
- Such centres do not necessarily already have but will have the good potential for **establishing links for innovation and transfer**, because the innovation and transfer should be research driven by clinical needs that benefits patients.
- **Integrating innovations** from outside the centres is not necessarily given but should be feasible depending on the management and the strategy.
- These are certainly valuable **Education and training** facilities for researchers as well as students, which can be fostered via collaboration with universities and hospitals. Again, the challenge is the pure one-nation approach.

Threats

Criteria, that are potentially difficult to be fulfilled or cannot be fulfilled and that might hamper the improvement of useful research on medical applications of ionizing radiation in medicine or the corresponding radiation protection for the individualised patient benefit throughout Europe are listed in this category:

- As this option describes centres on one topic in various locations there is a big threat that the centres are competing, and that **infrastructures and resources are spent twice or more**. This might **waste resources** in terms of a European strategy of research.
- There is a potential for different **standards or data formats for biobanks, open data repositories** but maybe also for **high standards of care and leadership.**

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In summary:

Option 4) A CoE as described in 2) but distributed throughout Europe; up to one per country, probably requiring high levels of buy-in from national governments.

Strengths	**Weaknesses**
- Efficient management of an open access data repository; - Suitable management and easy access to biobanks in the centres; - Management strategy and leadership; - Feasible national labelisation/ certification/ accreditation, but it would be challenging to achieve international wise; - Open access technology/ equipment would be available; - Active network of researchers. - localised impact on society, which might sum up to a European wide impact; - These CoEs can help to guaranty sustainable access to technology; - Excellent research can be fostered; - Knowledge of diseases including the associated biology and fundamental mechanisms of disease.	- It is not likely to provide any high standards of care, integrated practice unit; - It would not be an ideal integrated healthcare delivery model; - Not so much translational research to care will be performed. - It would not be helpful for structuring a European Health Care support system. - It does not necessarily provide direct medical care including personalised medicine; - There might not be a strong tendency for clinical research and to include hospitals throughout Europe within the research approaches. - It is most probable that infrastructures as well as resources will be doubled. - There might be competition between CoEs and no clear single contact for researchers.
Opportunities	**Threats**
- It can cover in principle the full range of required Interdisciplinarity, with a lot of constructing efforts; - It has good potential for establishing links for transferring innovation; - Integrating innovations from outside the centre should be feasible depending on the management and the strategy; - It is certainly a valuable Education and training facility.	- The centres might be competing, and infrastructures and resources are spent twice or more; - There is a potential for different standards or data formats for biobanks, open data repositories but maybe also for high standards of care and leadership

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Option 5) Disease-oriented CoEs as describe in 3) but distributed throughout Europe; up to one per country (with the same requirements as 4 above).

Strengths

For this option, we assume that the following criteria are fulfilled and can thus be assumed as strengths of this option:

- It can be assumed that such disease-oriented CoEs, one per country can provide efficient management of **open access data repositories** as well as a high productivity because of more shared common research interests and concentrated expertise. However, there might be different repositories for different countries and different diseases.
- This option might include a suitable management and easy access to one or more **biobanks**, due to an overlapping research focus and e.g. easy gathering and transportation/storage of bio-samples.
- Disease-oriented CoEs, one per country shall have a **management strategy and leadership**.
- (Inter-)national labelisation/ certification/accreditation would be feasible, but **(Inter-)national labelisation/ certification/accreditation** might also in this case be difficult due to heterogeneous situations across countries. However, one centre per country could be certified.
- **Open access technology/ equipment** would be available if the CoEs allow it and are equipped accordingly. Technological equipment might be focused on biological or medical technology. The access would be feasible in terms of sharing and implementing funding, management, maintenance as well as close collaboration.
- Within any of the localised centres, it is convenient to establish and maintain an active **network of researchers**, at least within each of the centres.
- Such CoEs will most probably have localised **impact on society** based in parts on potential **translational research for care,** which might sum up to a **European wide impact.**
- **Excellent research** including **clinical research** can be fostered by and performed in such integrative centres using the guidance of the EURAMED rocc-n-roll SRA.
- These CoEs can help to **guarantee sustainable access to technology and to medical care products**, while for the technology this would be unclear as the CoEs are not technology driven.
- **Knowledge of diseases including the associated biology and fundamental mechanisms of disease** will be given depending on the setup scenario of the centres as they are disease oriented.
- Such centres will most probably be able to help to structure the **European Health Care support systems.**

Weaknesses

In case there are relevant limits in fulfilling the criteria or a complete failing on a criteria this is listed here as a weakness:

- It is unclear whether a focus on **personalised medicine can be achieved**.
- There might be a potential lack on **technological equipment.**
- As every nation will have its own centre it is most probable that **infrastructures as well as resources** will be **doubled**.

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- There might be **competition between CoEs and no clear single contact for researchers**.

Opportunities

As opportunities we define criteria which could be fulfilled but are not necessarily easy to fulfil in the option to be evaluated or such aspects which will allow dedicated positive developments based on some criteria:

- Such disease-oriented centres can be covering in principle the full range of required **Interdisciplinarity**, but it is not given per se. It needs a lot of effort to construct the centres that way that especially clinical expertise, technological and biological expertise are all represented. And for the approach of disease- oriented centres it needs specific efforts to include the technical expertise.
- Such centres do not necessarily already have but have a great potential for **establishing links for innovation and transfer**, because this innovation and transfer should be research driven by clinical needs that benefit patients. Especially the transfer into clinical European- wide use is however challenging if the centres are national centres considering the differences in clinical care throughout Europe currently existing.
- **Integrating innovations** from outside the centres is not necessarily given but should be feasible depending on the management and the strategy.
- The centres are certainly valuable **Education and training** facilities for researchers as well as students, which can be fostered via collaboration with universities and hospitals.
- The proposed structure will be most probably research centres (one per disease and per country), thus does **not necessarily** provide any **high standards of care, integrated practice unit**, nor **integrated healthcare delivery models,** however, the disease focus might help providing these for some of the diseases in question.

Threats

Criteria, that are potentially difficult to be fulfilled or cannot be fulfilled and that might hamper the improvement of useful research on medical applications of ionizing radiation in medicine or the corresponding radiation protection for the individualised patient benefit throughout Europe are listed in this category:

- As this option describes centres on one topic in various locations there is a big threat that the centres are competing, and that **infrastructures and resources are spent twice or more**. This might **waste resources** in terms of a European strategy of research.
- There is a potential for different standards or data formats for **biobanks, open data repositories** but maybe also for **high standards of care and leadership** practices.

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In summary:

Option 5: Disease oriented CoEs as describe in 3) but distributed throughout Europe; up to one per country (with the same requirements as 4 above),

Strengths	**Weaknesses**
- Efficient management of an open access data repository; - Suitable management and easy access to one or more biobanks; - Efficient management strategy and leadership; - Feasible national labelisation/ certification/ accreditation, but it would be challenging to achieve international wise; - Open access technology/ equipment would be available; - Active network of researchers; - Localised impact on society based in parts on potential translational research for care, which might sum up to a European wide impact; - Excellent research including clinical research can be fostered; - These CoEs can help to guarantee sustainable access to medical care products; - Knowledge of diseases including the associated biology and fundamental mechanisms of disease will be given. - These CoEs are probably helpful to structure the European Health Care support systems.	- It is unclear whether a focus on personalised medicine can be achieved; - There might be a potential lack on technological equipment; - Infrastructures as well as resources might be doubled among national centres; - There might be competition between CoEs and no clear single contact for researchers.
Opportunities	**Threats**
- It can cover in principle the full range of required Interdisciplinarity, with a lot of constructing efforts; - It has good potential for establishing links for transferring innovation; - Integrating innovations from outside the centre should be feasible depending on the management and the strategy; - It is certainly a valuable Education and training facility; - High standards of care, integrated practice unit, integrated healthcare delivery models not for all diseases, but for some of the diseases in question.	- The centres might be competing and that infrastructures and resources are spent twice or more; - There is a potential for different standards or data formats for biobanks, open data repositories but maybe also for high standards of care and leadership.

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Option 6) CoEs as described above per country but focused on one topic and disease (example: imaging and oncology) to develop research activities linked to recommendations reported in the EURAMED rocc-n-roll SRA.

Strengths

For this option, we assume that the following criteria are fulfilled and can thus be assumed as strengths of this option:

- It can be assumed that such disease- and topic- oriented CoEs, one per country covering different topics and diseases can provide efficient management of **open access data repositories** as well as a high productivity because of more shared common research interests and concentrated expertise. However, there might be different repositories for different countries and different diseases.
- This option might include a suitable management and easy access to one or more **biobanks**, due to an overlapping research focus and e.g. easy gathering and transportation/storage of bio-samples.
- Disease- and topic- oriented CoEs, one per country shall have a **management strategy and leadership**. In the ideal case, there would be **one CoE umbrella structure with one research and management strategy and leadership.**
- (Inter-)national labelisation/ certification/accreditation would be feasible, but **International labelisation/ certification/accreditation** might also feasible if there is an umbrella CoE structure interlinking the CoEs.
- **Open access technology/ equipment** would be available if the CoEs allow it and are equipped accordingly. Technological equipment might be focused on certain technology in each centre but altogether the whole system could provide all relevant infrastructures. The access would be feasible in terms of sharing and implementing funding, management, maintenance as well as close collaboration.
- These CoEs can help to **guarantee sustainable access to technology and to medical care products**.
- Within any of the localised centres, it is convenient to establish and maintain an active **network of researchers**, at least within each of the centres. In addition, the network could be **extended throughout all CoEs**.
- An established network of such CoEs can have a large **impact on society, locally and internationally, including a European Impact.** This can be in parts be based on potential **translational research for care.**
- **Excellent research** including **clinical research** can be fostered by and performed in such integrative centres using the guidance of the EURAMED rocc-n-roll SRA.
- **Knowledge of diseases including the associated biology and fundamental mechanisms of disease** will be given depending on the setup scenario of the centres especially by those that are disease- oriented.
- The proposed structure will be most probably clinical centres as well as research centres, thus can efficiently provide **highest standards of care, integrated practice unit**, and partly **integrated healthcare delivery models.**
- Such centres will most probably be able to help to structure the **European Health Care support systems.**
- A focus on **personalised medicine can be achieved,** if the umbrella structure and the corresponding strategy can be set-up.

This project has received funding from the Euratom research and training programme 2019-2020 under grant agreement No. 899995.

Weaknesses

In case there are relevant limits in fulfilling the criteria or a complete failing on a criterion this is listed here as a weakness:

- There might be a potential lack on **technological equipment** in a single country**.**
- There might be **competition between CoEs.**

Opportunities

As opportunities we define criteria which could be fulfilled but are not necessarily easy to fulfil in the option to be evaluated or such aspects which will allow dedicated positive developments based on some criteria:

- Such disease- and topic- oriented centres can be covering in principle the full range of required **Interdisciplinarity**, but it is not given per se. Especially, with the topic focus, there might also be a lack of interdisciplinarity. It needs a lot of effort to construct the centres that way that especially clinical expertise, technological and biological expertise are all represented.
- Such centres do not necessarily already have but have a great potential for **establishing links for innovation and transfer**, because this innovation and transfer should be research driven by clinical needs that benefit patients. Especially the transfer into clinical European-wide use is however challenging considering the differences in **standards of care and leadership** throughout Europe currently existing.
- **Integrating innovations** from outside the centres is not necessarily given but should be feasible depending on the management and the strategy.
- The centres are certainly valuable **Education and training** facilities for researchers as well as students, which can be fostered via collaboration with universities and hospitals.

Threats

Criteria, that are potentially difficult to be fulfilled or cannot be fulfilled and that might hamper the improvement of useful research on medical applications of ionizing radiation in medicine or the corresponding radiation protection for the individualised patient benefit throughout Europe are listed in this category:

- As this option describes centres, which **need to collaborate strongly on their common goal**, they **need to have a common strategy and a defined common management plan and structures**. If that is not working out, many of the potential strengths and opportunities might turn into problems or cannot be realised.
- There is a potential for different **standards or data formats for biobanks, open data repositories but maybe also for clinical care practices**, which could occur if the umbrella structure is not efficient.

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In summary:

Option 6) CoEs as described above per country but focused on one topic and disease (example: imaging and oncology) to develop research activities linked to recommendations reported in the EURAMED rocc-n-roll SRA.

Strengths	**Weaknesses**
- Efficient management of an open access data repository; - A suitable management and easy access to a biobank; - Management strategy and leadership; - Beyond national labelisation/ certification/ accreditation, International labelisation/ certification/ accreditation might also feasible; - Open access technology/ equipment; - Sustainable access to technology and to medical care products; - Network of researchers within and beyond the centre; - Large impact on society, locally and internationally, which can be partly based in potential translational research for care; - Excellent research including clinical research can be fostered; - Knowledge of diseases including the associated biology and fundamental mechanisms of disease will be given; - Providing efficient highest standards of care, integrated practice unit, and partly integrated healthcare delivery models. - It can help to structure the European Health Care support systems; - A focus on personalised medicine can be achieved.	- There might be a potential lack on technological equipment in a single country. - There might be competition between CoEs.
Opportunities	**Threats**
- It can cover in principle the full range of interdisciplinarity; - Good potential for establishing links for innovation and transfer; - With suitable management and strategy, integrating innovations from outside the centre is feasible; - It is certainly a valuable Education and training facility for researchers as well as students.	- It is critical and challenging to achieve the common goal, strategy and a defined common management plan and structures; - Potential risks in achieving standardised data formats for biobanks, open data repositories and for clinical care practices.

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5. Conclusion

As it could be elaborated in the previous chapter within the SWOT analysis, each of the options presented previously in deliverable 4.1 has advantages and disadvantages, of which some will definitely be relevant at the startup phase, others might occur or not. This is described for each option and then summarised in corresponding tables. As it can be seen, mostly we could refer to the criteria that were elaborated by the survey and the exchange and consultations with experts as represented in milestone 14.

The biggest challenge for option 1 is the potentially missing strategy and all related potential problems, for option 2 and 3 the biggest problem occurs due to the national focus of such a centre structure. This problem would not occur for options 4 and 5 but in this case different data formats as well as competition between centres together with the danger of doubling of resources and infrastructures and thus a reduced efficiency might be counterproductive. The option 6 offers the best strengths and opportunities, but only if there will be an efficient umbrella structure and a clear common goal and strategy established to manage all these centres. This certainly offers – also in terms of personalised medicine - the largest potential benefits for the research in Europe on medical application of ionizing radiation and the best possible clinical care for patients, but it is also connected with the largest needed effort establishing the umbrella structure as well as a common strategy and management.

For the authors, the option 6 with the umbrella structure is the most appealing and promising and seems to be worthwhile the efforts. It seems to be helpful to establish such an umbrella structure through an institution having experience in running large scale projects in the clinical context on a European level and doing similar management things in similar applications. Certainly, we need the agreement of the whole community to identify the ‘best’ option.

This project has received funding from the Euratom research and training programme 2019-2020 under grant agreement No. 899995.

6. Reference

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