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D4.1 Options for Centres of Excellence (CoE) for medical applications of ionizing radiations and medical radiation protection research

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Abbreviations

CoE Centre of Excellence

RTO Research and Technology Organization

TRL Technology Readiness Level

RI Research Infrastructures

ESFRI European Strategy Forum on Research Infrastructures

EMBL European Molecular Biology Laboratory

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1. Introduction

If one uses “Centre of Excellence” (CoE) as a keyword in the title to identify published documents during the period 2021-2022 using Web of Science software, more than 100 papers (review, articles and abstracts) are found which are mainly focusing on aspects of medicine and medical sciences. Using CoE as a topic, the number increases to more than 850.

Centre of Excellence is not a single well-defined label but has emerged as a concept from the USA many years ago as part of competition and leadership between public and private medical institutions. The objective was clearly to easily identify a team of experts with expertise in certain areas having access to up-to-date equipment and using protocols that implement translational activities “from bench to bedside”, resulting partly in success stories in medical care to ensure the highest benefit for the patients.

It was taken up rapidly first in the area of Higher Education and Research, mainly by medical universities, and was then extended to other domains of science, without a consensual definition and a common understanding. Frequently, we observe that where it is applied at higher governmental or national level, the appellation can change to “center of reference” or “disease center” as “Comprehensive Cancer Centres” (CCC) (Eggermont *et al* 2019; Oberst, 2019) strongly connected to hospitals for example, depending on the management issued from the health sector, or for example “Center of Biomedical Research Excellence” (COBRE) (Oxford *et al*, 2020) in the research sector. But even there definitions vary quite strongly between different countries for example as was also visible in a survey about conceptualising CoE that has been performed by the EURAMED rocc-n-roll project within task 4.1 “Infrastructures for research on medical applications of ionizing radiation and corresponding radiation protection”. This survey will be referred to as “the CoE survey” in the following text.

The label CoE was initially developed as a self-declared label with a marketing purpose, used as a label for communication and management. It seems unclear if the communication was oriented primarily to the patients, to the internal team or to the external community, but it is obvious that the strategy was oriented to building a very positive image in three words “Center of Excellence” and raising a claim of leadership as the best place (with the best team). Then, in literature, the concept evolved quickly, became more credible and less declarative and was built on some criteria; however, the list of the most important can vary greatly.

Of course, as this phenomenon is common and was taken up for nearly all research domains, it was also applied in the medical area and, in this field, developed in two directions. First, describing “excellence” in clinical care and second, linking it to the possible extent of clinical research. For evaluation purposes, “excellence” is, first of all, based on the team and its expertise and, second, the link that they build for transfer and innovation outside of the basic research area.

A CoE generally indicates a highly specialised team which constitutes a pool of expertise linked to an infrastructure and expertise, or combinations thereof, which is not available elsewhere, often at a national level but also at a regional level, and that is often tasked with the leadership

of communities: This definition is too short and not always accepted and shared throughout Europe.

In some countries, governments have tried to regulate the system to identify the best universities and research organisations at least for certain topics for potential direct financial support (not linked to projects). The general idea is to focus efforts (money) for the benefits of a few centres through a competitive process (specific calls dedicated to universities covering all domains) This point illustrates clearly that the concept is also fundamentally related to its financial/economic sustainability.

The general objective of task 4.1 is related neither to the inventory of one or more suitable CoE(s) of medical applications using ionising radiation linked to identified diseases through their research record or their national recognition (whatever name is used) by their countries as medical universities/hospitals; nor is it to build a network between these and a set of existing Medical Radiation Research Infrastructures (MRRIs) in the area of the radiation protection. No evaluation has to be done to compare them regarding the sets of criteria used by their management, their skills, and their suitability to contribute to addressing a research priority, which will be proposed through the upcoming EURAMED rocc-n-roll SRA. Instead the objective is to pave the way to find necessary or desirable infrastructures that would help to foster the fundamental research that is going to be proposed in the SRA as well as the required translational approaches, and the supportive environment.

Therefore, a number of tasks has been fulfilled: The first step, a “literature review”, resulted in a selected list of related documents (reviews, articles and reports) which are connected to the concept of CoE but not always to our thematic “medical applications of ionising radiation and medical radiation protection research”. It is not an evaluation of each document nor a synthesis of the actual landscape in each country regarding this medical area.

The second step consisted of a survey on CoE among the consortium of the EURAMED rocc-n-roll project and beyond in order to analyse the various understandings about CoE definitions and their associated criteria. The survey is still open, and its results will also feed into D4.2 “SWOT for establishment of CoEs in medical applications of ionizing radiations”. With the data already collected, we have identified challenges and requirements regarding the actual landscape across Europe, as well as people’s assumptions about potential options for CoEs and the discrepancies of understanding in different regions as well as among different disciplines. The trends that were identified have thus already been taken up in this deliverable.

Our objective in this report is to answer what could be options for a future CoE system dedicated to medical applications of ionising radiation and medical radiation protection research based on the observation of “what exists in Europe today?” and “what is needed?”. The complementary questions “what is missing?” and “what can the EC reasonably do to help our research community reach such ideal CoEs?” constitute a set of four questions which is assumed to help the implementation of relevant research as proposed by the SRA.

In this deliverable, we develop our proposal (Section 5) based on information extracted from the literature review (Section 2) and information coming from the community, providing its own analysis of needs issued from actual configurations and experiences (Sections 3 and 4). We

finally link this work (Section 6) to the next deliverable D4.2 where recommendations will be made based on a more complete SWOT analysis.

2. Variability in definitions, characteristics and objectives

“Excellence” in research is often linked with higher education due to the actual landscape shaped in part by the universities (medical faculties / university hospitals and other disciplines) when this organisational approach exists in a country. This could allow developing a concept for the evaluation depending on the objectives of governments and their evaluators, objectives in teaching, in management, in student performance, in innovation, in clinical care, etc. Therefore, the relevance of documents on CoE and their diversity are connected to their priorities/objectives. Four different cases are listed below:

- A) Centre of Excellence in research (not only oriented to medical areas/applications),
- B) Centre of Excellence in higher education for medical studies (University Hospitals),
- C) Centre of Excellence in clinical research (all diseases),
- D) A disease related Centre of Excellence focused on care (centred on the patient) (and sometimes partially linked to the inside and outside corresponding research).

To illustrate this, two slightly different examples based on the “D” (Elrod *et al*, 2017; Pakizegee *et al*, 2019) approach are provided below:

1) A CoE is an area of health care specialisation in a medical centre that is recognised by the medical community as providing the highest level of expertise in care. A CoE is associated with a clinical service and should meet at least the following criteria:

- A comprehensive clinical continuum of care
- Quality differentiation of services and technology
- Commitment to education and research
- Clinical and administrative leadership
- Community impact and market prominence

2) A medical CoE means more focused care in a critical medical field, providing access to a full range of treatment options and quality care. It means that medical doctors are focused mainly on improving treatment protocols, programmes, and outcomes for patients. Such a CoE includes an integrated practice unit together with an integrated healthcare delivery model connected to the highest level of research in a particular field. Finally, the medical doctors are highly qualified in their specialty and are entrusted with training future doctors in the field.

While these two approaches are clearly “patient-oriented”, and also oriented to medical doctors, there are nevertheless quite different. The first clearly has a management approach of services and aims at an economic impact without focusing on a particular medical field. Both are connected to research and education, but the commitment appears as a secondary objective.

Considering case “B” above, medical universities/university hospitals are often the obvious target, but it is observed that all medical specialties could sometimes be taught with fewer

interactions with other science domains (chemistry, physics, informatics...) developed in other universities to conduct an integrative multidisciplinary research. These institutions are linked to hospitals, so also oriented to (but not centred on) patients. Students have the opportunity to learn their practice with chances to selectively participate in research activities. In a first approximation, they are centred on education and research first.

Considering case “A” above, the variability of institutions including RTOs (specialised knowledge organisations dedicated to the development and transfer of science and technology to the benefit of the economy and society) is large but the common understanding shows that those research institutions are not sufficiently connected to hospitals and patients.

Considering case “D” above, which are maybe the most frequent observed CoEs, the definition/orientation of the objectives by the disease is sometimes controversial: “Cancer Centres” or “Prostate Cancer Centres” and more in details behind the clinical criteria the aspects of the diagnostic pathway versus the therapeutic pathway (Wirth *et al*, 2020; Albersten, 2020)

Approximately, this classification goes from basic research, with low TRL to progressively nearer to the patient from the medical basis to the care activities with higher TRLs.

Applying an overarching view, we see that there are also other definitions and forms of organisations which might be related to CoEs. For instance, in our CoE survey people mentioned a range of keywords beyond what have been mentioned above: Interdisciplinarity, innovation, economic impact, experience, network of researchers. Beside CoEs, there are so-called research infrastructures and networks of excellence.

Referring to the EC approach and definition of Research Infrastructures described below (in italics) (https://ec.europa.eu/info/research-and-innovation/strategy/strategy-2020-2024/our-digital-future/european-research-infrastructures_en), even if the question of the patient is not invoked, it appears that it could be relevant to ask if this definition is applicable to our shared understanding of the main qualities of a CoE, which could be a particular topic with a particular context such as a Medical Radiation Research Infrastructures (MRRI).

Research Infrastructures (RI) are facilities that provide resources and services for research communities to conduct research and foster innovation, RIs could be opened to host external researchers to realize their own research project. RIs could be single-sited, distributed, or virtual and could include:

- *major scientific equipment or sets of instruments (sometimes unique)*
- *biobank and or connected databanks*
- *computing systems and communication networks*

The Commission *defines, evaluates and implements strategies and tools to provide Europe with world-class sustainable Research Infrastructures. It also ensures that these research infrastructures are open and accessible to all researchers in Europe. Key objectives are:*

- *reduce fragmentation of the research and innovation ecosystem*
- *avoid duplication of effort*
- *better coordinate the development and use of Research Infrastructures*

- *establish strategies for new pan-European, well-established intergovernmental or national Research Infrastructures*
- *join forces internationally to construct and run large, complex or expensive infrastructures, respond to global challenges and/or foster combining skills, data and efforts of the world's best scientists*
- *foster the innovation potential of Research Infrastructures by making industry more aware of opportunities offered to improve their products and by the co-development of advanced technologies*

On the other hand, in the CoE survey, 66% participants (33 out of 50 individuals) reported “No”, when being asked about if they have easy access to research infrastructures among Europe (Fig. 1). The reasons include exclusive accessibility through EC project, information missing, highly depend on the setup of consortium and project et al. Therefore, sharing and management of RIs at an EU level can and should be definitely improved.

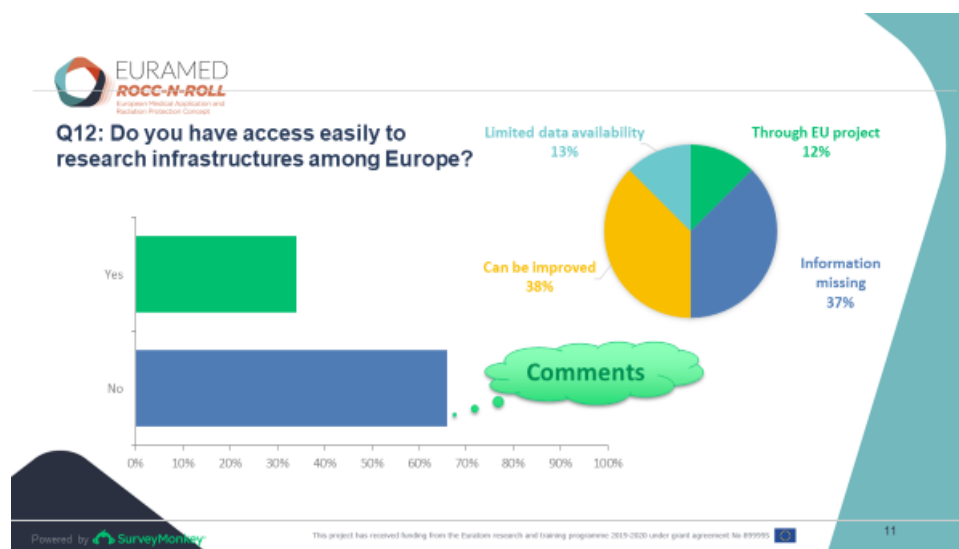


Fig. 1 Current situation of accessibility to research infrastructures among Europe

It appears that it could be relevant to ask if this definition is applicable also to a shared understanding of the main qualities of a CoE, even if the patient is typically not taken into account. In this case, the infrastructure would in this context need to deal with particular topics in a dedicated context such as a Medical Radiation Research Infrastructures (MRR).

As the ESFRI system already exist, with very few RIs oriented to health sciences, it seems evident that we find here the same approach of recognition based on some very similar objectives and criteria.

3. What is needed?

In the CoE survey, it has been indicated that 60% of participants (33 out of 50 individuals) would like to orientate their future research to the clinical application; more than 70% of participants think potential CoEs in the field of medical application of ionising radiation should focus on clinical application/ translational medicine (Fig. 2).

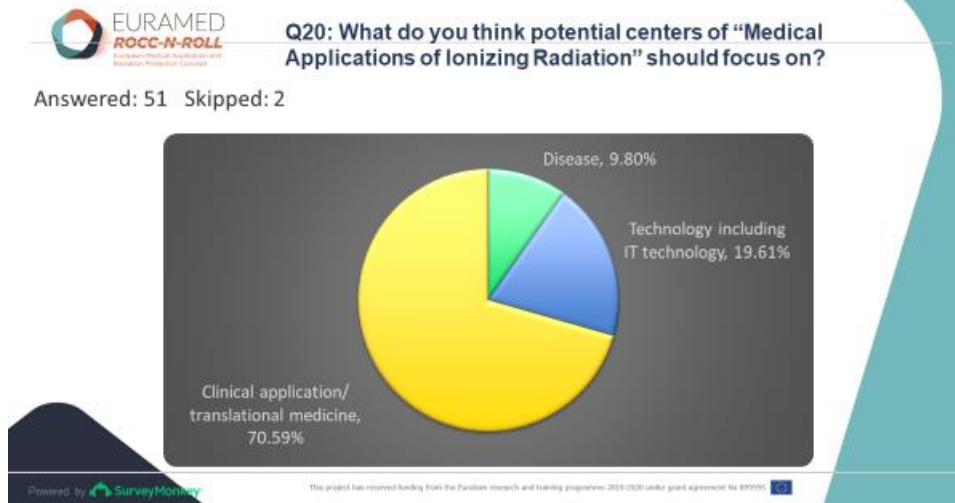


Fig. 2 Distribution of answers on potential CoE of "Medical application of Ionizing Radiation"

We need to strengthen the connections and cooperation between the relevant stakeholders and associations in the community dealing with medical applications of ionising radiation in order to reach a critical mass of expertise across disciplines. This can either be a team of experts in the same place or in a network, as moving much expertise from various nationalities and specialties could be difficult and concentrating the large variability of equipment already existing is unrealistic. More than 75% of participants of the CoE survey indicated their preference for working among changing networks while participating in various projects (Fig. 3). In their current projects, more than 60% of participants are working among a network of researchers while less than 8% of participants are working in a network of infrastructures and around a quarter of the participants are working in a network of both researchers and infrastructures. Most recently named centres of excellence have a regional, sometimes national, rather than transnational remit. One notable exception would be the EMBL, which sustains movement of personnel though major direct national funding.

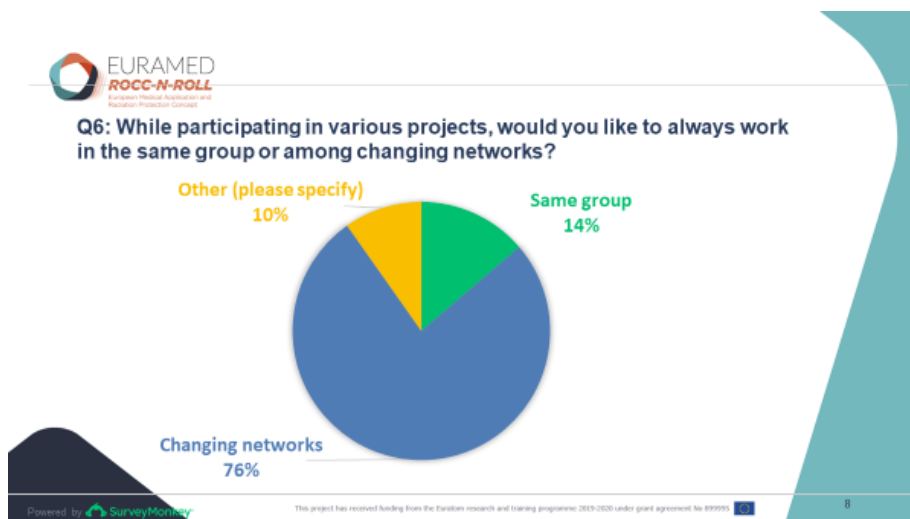


Fig. 3 Distribution of preference of networking while working on projects

To provide the most efficient research throughout Europe in terms of benefit for the patients in all European countries, it is of utmost importance to realise that research on medical applications of ionising radiation must necessarily be mainly driven by medical needs and thus

needs to allow the inclusion of clinical researchers. Accordingly, when indicating the most helpful research driver for European patients (Fig. 4), 56% of participants expect major benefit for European patients if research are driven by “Clinical application”. Meanwhile, 26% have chosen “Technology including IT technology” and 18% “Disease”.

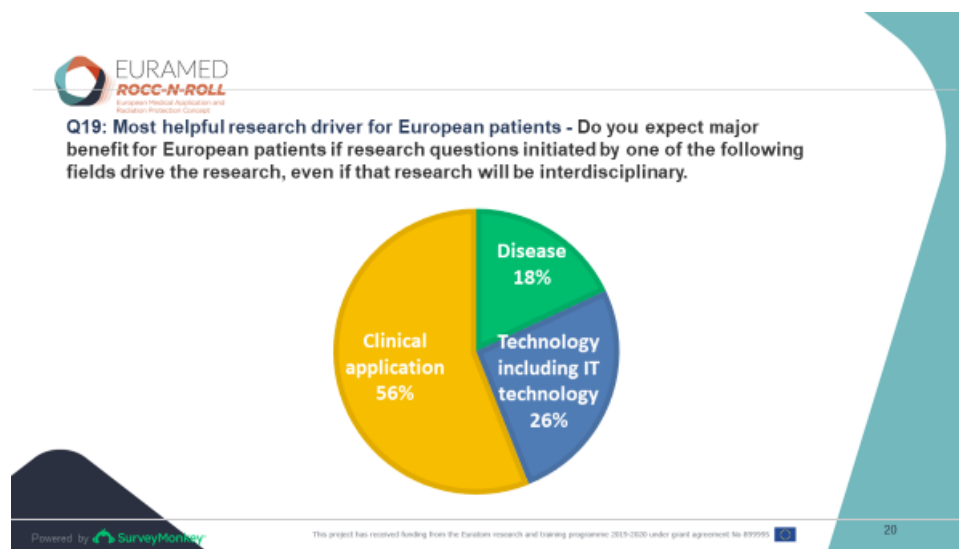


Fig. 4 Distribution of answers about most helpful research driver for European patients

As a first consequence of these observations, a potential CoE system naturally will have the mission of training and transfer of skills. A second and maybe more important key of success will be an organisation which facilitates sharing and managing the use of data across borders and institutions with a common strategy, common rules, standardisation and a coordination in resources to ensure safe and trustworthy mobility of data. The objective of this approach is to generate a virtuous circle for data from “clinical activities to research and of course ensure the reciprocity of producing exploitable data for clinicians to contribute to improving patient care through personalized medicine. With new analytical techniques being available the volume and richness of data is essential for the application of machine learning and AI technologies and the aggregation of sufficient qualities of data for the discovery of for example small effect sizes is critical. Similar approaches of standardisation and data aggregation across Europe have already been successfully tried in the rare disease domain and radiation medicine similarly needs the mobilisation of such data across the community.

4. Lessons learnt and first observations

There are various existing papers dealing with CoEs, what they could be used for, how they could be configured and what could be effects.

The article by Manyazewal *et al* in 2022 “Conceptualising centres of excellence: a scoping review of global evidence” shows a synthesis of numerous papers focused on the concept of CoE in and outside the healthcare area. The vocabulary used in order to express the general objectives and to meet targets to achieve excellence is strongly organised around four thematic areas: higher education, research, innovation, and transfer to industry. Added to those, the concept of excellence implies that some pillars should be developed sufficiently: specialised expertise and multidisciplinary skills, infrastructures, and equipment, quality of services,

external label recognition, leadership, organisational structure, strategy and policy, collaboration and partnership, sustainable economic model (funding and financial mechanisms).

This short description could be the basis for developing criteria, but they could be fused around the impacts they should have: scientific, individual patient care, economic and social impact on a European level (when we look for healthcare and public health).

Regarding the domain of medical applications of ionising radiation, which seems focused only on some diseases, the feasibility of merging the interests of care activities including diagnostic and therapeutic aspects linked to clinical research as a CoE (mixture of types C and D) seems to be the most frequently observed case. This type of CoE, not enough developed, for example, in basic mechanisms, in vitro, preclinical studies, has no possible other choice to be linked to external research infrastructures which develop more fundamental and upstream linked activities.

It seems that existing CoEs (according to their own definition) tend to be localised (regionally, sometimes nationally) if they have a patient-centred focus. This results in limited possibilities to benefit the full European population, as patients and their funding cannot easily be transferred cross borders. While it is intrinsically difficult to implement a dominantly patient-centric view on a European scale, such restrictions do not exist, or are less problematic and severe in the exchange of patient data and research data across national boundaries.

5. Possible options

Issued from the observed CoEs that have been described in the literature review, the definitions that have been reported, as well as trends deduced from some relevant results from the survey, we list below, in short, what are the global trends of requirements, which could be applied to potential options:

- 1) A potential CoE system should be centred on research,
- 2) A potential CoE system should most probably be oriented to personalised radiation medicine,
- 3) A potential CoE system should be multidisciplinary, largely more than medical specialties where skills could be aggregated and shared,
- 4) A potential CoE system should be inclusive and attractive to clinicians.

A CoE would need to have a critical mass regarding:

- i) facilities and a large variability of equipment, technologies maybe including AI featuring technologies
- ii) an open databank managed and oriented to real shared activities, meaning that the CoE must provide and share relevant data
- iii) researchers issued from a large spectrum of needed specialties (including for example epidemiology, radio-genomics, radiobiology, disease related biology, clinicians, radiologists,

nuclear medicine experts, radiation therapy experts, medical physicists) guaranteeing multidisciplinary approaches in basic and clinical research of IR applications and RP.

Finally, a CoE should have a broad coordination, a strategy, and a roadmap (plan).

The options are:

- 1) No dedicated CoE but only networks e.g. between existing technology based or disease related national centres or infrastructures,
- 2) A unique CoE as described above localised in one country covering all the requirements to develop research activities reported in the upcoming EURAMED rocc-n-roll SRA,
- 3) A unique disease-oriented CoE as described above and in 2) in Europe (one per disease),
- 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,
- 5) Disease-oriented CoEs as described in 3) but distributed throughout Europe; up to one per country (with the same requirements as 4 above),
- 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.

For the options 4, 5 and 6, a link between localised CoEs should be developed. The concept of a network of CoEs answers the problem of the low international mobility of patients but permits a possible high mobility of data, extended exchange between researchers and the possibility of centralised or distributed analysis. A high level of sharing experiences and skills is an important aspect for the patients' benefit across Europe. It is the way to obtain a critical mass with a broad coordination which organise the global view and strategy safeguarding the interests of the patients and e.g. the orientation on personalised medicine.

6. Perspectives: towards the SWOT analysis

The present status about requirements and options can be developed only after a complete SWOT analysis. Keeping in mind that actually it is not realistic to expect patients to move easily across national borders, the idea of a clinical CoE or international referral centre is neither practical nor achievable, even if desirable. The recruitment of experts and specialists to a localised CoE in a member state is linked to its stability and sustainability. It would determine whether a relatively short-term international relocation would be attractive across Europe. Timeframes and commitment to funding would have to be important to achieve this.

As stated before, the most efficient research throughout Europe in terms of benefit for the patients in all European countries requires research on medical applications of ionising radiation and must necessarily be mainly driven by medical needs and thus needs to allow the inclusion of clinical researchers, as in some university hospitals when this system exists in a country (Ovseiko *et al*, 2012). A CoE system needs thus to be inclusive in this respect.

Very large, rare and expensive equipment might be useful to be located in one or more relevant research infrastructure(s) that already exist. It implies the need for human expertise, in order to fulfil its promise which is not localised in actual CoEs. Consequently, we suggest that movement of data, bio samples, protocols to diffuse, E&T programs across national borders needs to be fostered by such centres to provide added value to the community. In addition, the corresponding data processing agreement, data protection, ethical approval of using patient data, and managing the data sharing successfully both technically and administratively are further important issues to be considered. With centralised training added to the mix, this might prove a valuable and long lasting benefit.

Here, we have not developed the aspects linked to the evaluation but moving from self-nominated to an external recognition will be a part of the solution towards a common understanding and confidence in a CoE system from the community as well as from the patient.

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