Facilitating macro-regional scope and link up to socio-economic actors of Research Infrastructure in the Danube Region (ResInfra@DR)

WP5: Pilot Actions

PILOT ACTIVITY 2:

Support in designing/developing of the Nuclear Medicine Center at the Horia Hulubei National Institute for Physics and Nuclear Engineering, Romania. Final Report

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Contents

Abbreviations

CCR - Radiopharmaceutical Research Centre

ELI NP - Extreme Light Infrastructure - Nuclear Physics

ERDF - European Regional Development Fund

ICNAS - Instituto de Ciências Nucleares Aplicadas à Saúde (Institute of Nuclear Sciences Applied to Health)

IFIN HH - Horia Hulubei National Institute for Physics and Nuclear Engineering

INTERREG - European Territorial Co-operation

IPA - Instrument for Pre-Accession Assistance

MHTC – Magurele High Tech Cluster

NMC - Nuclear Medicine Center

UEFISCDI - Executive Agency for Higher Education, Research, Development and Innovation Funding

1. Executive Summary

The peer learning exercise was implemented in accordance with ResInfra@DR Call for expressions of interest addressed to research organisations, research infrastructures and their parent organisations and the Terms of Reference for the Call for single experts or expert teams to participate in a ResInfra@DR support activity. The ResInfra@DR project ("Facilitating macro-regional scope and link up to socio-economic actors of Research Infrastructure in the Danube Region) was designed to strengthen Research Infrastructures (RI) active in the Danube macro-region (DR) and has run from January 2017 to June 2019. The project was funded under the INTERREG Danube Transnational Programme supported by European Union funds (ERDF, IPA) and co-funded by project partners or from national public co-funding and state contributions. For more detailed information about this project and its results, please consult: http://www.interreg-danube.eu/approved-projects/resinfra-dr.

The present report represents the result of ResInfra Pilot Activity 2 in Romania, which was aimed at providing support in designing/ developing the Nuclear Medicine Center (NMC) at the Horia Hulubei National Institute for Physics and Nuclear Engineering (IFIN HH) in Magurele. The report was elaborated by: Antero Abrunhosa, PhD, director at Instituto de Ciências Nucleares Aplicadas à Saúde (Institute of Nuclear Sciences Applied to Health), Coimbra, Portugal and Pal Mikecz, PhD, senior adviser at Medicopus Nonprofit Ltd./Kaposi Mor Medical Hospital, Kaposvar, Hungary (external experts), and Ioana Spanache, PhD, Ioana Trif and Raluca Ciobotaru from the Romanian Executive Agency for Higher Education, Research, Development and Innovation Funding (UEFISCDI).

The core element of this pilot activity consisted of providing ex-ante support to three planned or to be upgraded RIs (in our case, IFIN HH and Extreme Light Infrastructure - Nuclear Physics - ELI NP, participating as parent organizations) in countries of the Danube macro region. Throughout the activity, the supported entities have received recommendations and expert opinions free of charge, as expert fees and travel costs were covered by the ResInfra@DR project.

In this specific case, the Horia Hulubei National Institute for Physics and Nuclear Engineering (IFIN HH) and the Extreme Light Infrastructure – Nuclear Physics (ELI NP) have requested support in designing/ developing a Nuclear Medicine Center (NucMed Center) at IFIN HH, in order to capitalize on their scientific results in the field of nuclear physics and extreme light infrastructure, and in relation to the medical community.

In this context, the two external experts contracted by UEFISCDI documented on and analysed the existing situation, participated in virtual meetings with representatives from IFIN HH and ELI NP, as same as in an 1 ½ on-site visit, in order to be able to provide the beneficiary with tailor made recommendations, examples of good practice and steps for potential roadmaps. The case for this pilot activity was built around the following main components and challenges:

1. Design and development of the Nuclear Medicine Center at ELI NP and IFIN HH, with a focus on business models;
2. Operation mode of the Nuclear Medicine Center, with a focus on technology transfer.

Overall, IFIN HH looked for recommendations regarding important steps which can be undertaken for or activities that can contribute to the creation and development of the Nuclear Medicine Center. The experts' opinion and the suggested activities were considered important for the necessary set up of the structure and the operation mode of the Nuclear Medicine Center, both from a short term and mid-term perspective.

The recommendations followed a "critical friends" approach and did not follow a specified set of criteria as the action is not considered an evaluation. This approach allowed to provide context related knowledge to the IFIN HH leadership.

Below is a summary of the final recommendations which have resulted. A more detailed version is described further in the document.

Recommendation 1

The proposal for IFIN HH and ELI-NP would be to develop the Nuclear Medicine Activities around three different components:

Research and Development in radiochemistry and radiopharmacy. This should be based on the recent activities in the IFIN Radiopharmaceutical Research Centre (CCR).

Besides the research and development component, there is a need for a **Routine Radiopharmaceutical production**. This should be developed as an independent structure within the Radiopharmaceutical Research Centre (CCR), and has to take care of all the routine work towards patient investigations and radiopharmaceutical deliveries to laboratories from outside.

The third activity of the laboratory should be: **Nuclear Medicine Clinic** (NMC). This should be a state of the art centre, using the latest radiopharmaceuticals produced in IFIN.

Recommendation 2

The centre should be created using national and/or European funds. This would enable the centre to use the best methods in the country and, therefore, to become a centre of excellence which would lead the way for other centres. The centre should run as a non-profit organization, and the resulted income should be spent on R&D activities.

Recommendation 3

The centre should be built linked to the existing CCR to enable the local (on-site) radiopharmaceutical production, thus avoid, when appropriate, the strict pharmaceutical and transport regulations of so called commercial pharmaceutical production. At the very beginning, the centre should start with imaging radiotracers only aimed at diagnostic or therapy follow-up purposes, but at a later stage the Centre should be further developed to also

utilize therapeutic radionuclides, that will be produced at ELI-NP and prepared as radiopharmaceuticals at CCR.

2. Summary of the Pilot Activity

Pilot Activity 2 involved the launch of two international open calls. The first was meant to identify the beneficiaries of support and was released on the 1st of October 2018. And had two components, in accordance to the types of applicants it was aimed at: LOT 1: Ex-ante support of three planned or to be upgraded RIs or LOT 2: RI measures in countries of the Danube macro region (pilot activity 2 and subject of this EoI).

In Romania, the Call was published on the partner's website and also sent to relevant public institutions, research infrastructures and parent research infrastructures. As response, along with other 5 applications from other countries, one application was received from the Horia Hulubei National Institute for R&D in Physics and Nuclear Engineering (IFIN HH), who hosts the Romanian Node (Nuclear Physics) of Extreme Light Infrastructure (ELI-NP).

The addressed questions within the application and other related issues were clarified in advance by IFIN HH and UEFISCDI.

Following this result, UEFISCDI has started developing in collaboration with the representatives from IFIN HH and with support from ZSI, the project lead, a new Call, this time addressed to potential individual experts and teams of experts who could provide support to the previously selected Research Infrastructure. After several meetings and online consultations have taken place on this topic, UEFISCDI has elaborated the Terms of Reference adapted to the specific needs of IFIN HH.

Thus, the second open call was launched in March 2019 and published on UEFISCDI website https://uefiscdi.gov.ro/news-apel-pentru-experti-in-vederea-participarii-la-activitatea-pilot-din-cadrul-proiectului-resinfra-dr and RESINFRA@DR webpage http://www.interreg-danube.eu/news-and-events/project-news/3792. The call was addressed to international individual experts or teams of experts who could provide support to the team at IFIN HH/ ELI NP in designing/developing a Nuclear Medicine Center.

The main aim of IFIN HH and ELI NP was to capitalize from their scientific results in the field of nuclear physics and extreme light infrastructure, and in relation to the medical community, by developing the previously mentioned NucMed Center.

In this context, the contracted experts had to make an analysis of the current state of things, and make suggestions and recommendations regarding activities and steps which can be undertaken in order to develop the NucMed Center.

Therefore, the terms of reference invited applicants to address two main challenges together with their related questions, which were formulated in accordance with the needs and requests of the benefiting organizations, IFIN HH and ELI NP:

1. Design and development of the Nuclear Medicine Center at ELI NP and IFIN HH, with a focus on business models;
2. Operation mode of the Nuclear Medicine Center, with a focus on technology transfer.

More details regarding how the two challenges were defined, together with their affiliated core questions and subquestions, and types of recommendations requested from the experts, can be found in Annex no.2, containing the ToR document.

As a result of this second open call, two applications were received, from Mr. Antero Abrunhosa, PhD, director of the Institute for Nuclear Sciences Applied to Health (ICNAS) based at the University of Coimbra (Portugal), and from Mr. Pal Mikecz, PhD, senior adviser at Medicopus Nonprofit Ltd./Kaposi Mor Medical Hospital, Kaposvar, Hungary who were contracted by UEFISCDI to formulate specific recommendations to the challenges met by IFIN HH and ELI NP in designing NucMed Center.

The two experts were contracted starting with the 2nd of May, 2019.

During April 2019, a series of online meetings have taken place between the two external experts and the representatives from IFIN HH and ELI NP, in which the former were introduced to more in-depth information about the context of the NucMed Center, previous actions undertaken for its development, the already existing facilities, and about what was expected from them. This way, the two experts were able to address questions, obtain clarifications and get a better idea of what was intended exactly regarding the design and operation of the new Center.

The methodological approach for this exercise is comprehensive and consisted of: desk research (documentation about the RI), virtual meetings, and on site visit to IFIN HH and ELI NP.

3. Summary of the on-site visit

Further, between the 6th and the 7th of May 2019, took place the one and a half days on-site visit of the external experts and UEFISCDI representatives to the headquarters of IFIN HH and ELI NP. The agenda of the on-site visit is listed in Annex no.1. During the first day of the visit, the experts attended more in detail presentations of the scientific capacity of ELI-NP and IFIN HH, visited their facilities and premises, and had the chance to directly interact with different relevant stakeholders: Kazuo Tanaka, Scientific Director ELI NP; Dana Niculae, Director of the Radioisotope Department; Calin Ur, Technical Director for the implementation phase at ELI; Dan Stutman, Director of the Experimental Department – ELI; Elena Dumitrascu and Cristian Iftimoaie from the National Authority for Quality

Management in Health, and other. Moreover, the two external experts also held presentations based on their experiences from their origin countries and regarding good practices which could be applicable to Romania's case.

The working sessions scheduled for the second half of the day, which also continued in the next morning, have proved to be of utmost importance, as they were dedicated to open discussions regarding the challenges encountered by the beneficiaries in developing the NucMed Center, the activities which were already undertaken, the existing facilities and the way in which these could serve the NucMed Center. Furthermore, it focused on potential business models, the operation mode of the NucMed Center and technology transfer. These sessions were a good opportunity for the representatives from ELI/ IFIN HH to address direct questions to the two experts, and for the latter to start drafting their recommendations. In addition to the working session, the second day was also dedicated to a visit of the premises and facilities of the Central Military Emergency University Hospital "Dr. Carol Davila", which will be an important future collaborator of the NucMed Center.

This event was attended by the representatives of ELI-NP, IFIN HH, the ResInfra@DR project team (from UEFISCDI) and other relevant stakeholders.

After the visit, the team analyzed the information obtained during it in order to have a better understanding of the RI and the relation between the latter and relevant stakeholders.

The news regarding the external experts' working visit to IFIN-HH and ELI NP at Magurele was announced on UEFISCDI's webpage (https://uefiscdi.gov.ro/news-resinfra-dr-pl-5-activitatea-pilot-2-vizita-de-lucru-a-expertilor-externi-la-eli-np-din-magurele) and on RESINFRA@DR webpage http://www.interreg-danube.eu/news-and-events/project-news/4095.

4. Information regarding the involved team

This Pilot Activity involved having a mixed team of external experts, representatives from IFIN HH and ELI NP, as beneficiaries, and ResInfra experts from UEFISCDI.

External experts

The **two external experts** were contracted as a result of an open call launched by UEFISCDI in March 2019. The Terms of Reference used in this sense can be consulted in Annex no.2 of the present report.

- Dr. Antero Abrunhosa, director at Instituto de Ciências Nucleares Aplicadas à Saúde, (Institute of Nuclear Sciences Applied to Health), Coimbra, Portugal;
- Dr. Pal Mikecz, Senior adviser at Medicopus Nonprofit Ltd./Kaposi Mor Medical Hospital, Kaposvar, Hungary.

IFIN HH / ELI NP

(http://www.nipne.ro/; http://www.eli-np.ro/ro/)

- Dr. Mihai Radu, Scientific Director at IFIN-HH;
- Dr. Dana Niculae, Head of Radiopharmaceuticals Research Center (CCR) of IFIN-HH;
- Dragos Seuleanu (EMBA), ELI-NP; Magurele High Tech Cluster, Executive Director.

ResInfra team involved – UEFISCDI and the other partners in charge of this activity

UEFISCDI – the Executive Agency for Higher Education, Research, Development and Innovation Funding, Romania (https://uefiscdi.gov.ro/)

- Ioana Spanache, PhD, Process Implementation Expert;
- Ioana Trif, Project Expert;
- Raluca Ciobotaru, Project Expert.

ZSI – Centre for Social Innovation (https://www.zsi.at/) – project lead

- Dl Felix Gajdusek, Project Manager.

Institute of Philosophy, Czech Academy of Sciences, (The Centre for Science, Technology, and Society Studies)

- Jan Balon, PhD, Work Package 5 leader.

5. Recommendations

The core element of this support action consisted of providing specific and practical recommendations and suggestions formulated by the external experts on steps that need to be undertaken in order to develop the Nuclear Medicine Center within IFIN HH and ELI-NP. Based on the findings and the conclusions drawn and on an in-depth methodological approach, a number of recommendations were formulated. The recommendations can be taken up by IFIN HH and ELI NP where deemed feasible and useful.

Moreover, the results of this pilot activity, as well as certain aspects regarding ELI NP's experience within the economic environment of the region, Romania were also presented during the RESINFRA@DR Know-How Exchange Forum in Bratislava, Slovakia, on May 23, 2019. The aim of the event was to identify, together with project partners and external experts, what are the transferable recommendations, as same as to share experiences and to create a basis for reflection for other relevant stakeholders.

The resulted recommendations[1] were formulated on two main challenges and their specific questions, as follows:

5.1. Challenge 1 – Design and development of the NucMed Center & potential business models

The IFIN HH and ELI-NP proposal for the planned research infrastructure - the NucMed Center is at a very early stage. The fundamental questions that need to be addressed are: what type of facility to build, how to link with the existing infrastructure, what are the main steps to be taken, what kind of business model should be followed and what kind of references could be used.

The main questions addressed:

1. **How can IFIN HH and ELI-NP capitalize in business on the scientific tradition, scientific results, and scientific future based on the most powerful laser in the world, so that it can create the proposed Nuclear Medicine Center?**

This is a challenge faced by many similar facilities throughout the world. Many of these found the possibility to have a Nuclear Medicine Clinic as a fundamental part of their strategy. It helps to fund the core structure, focus research on clinically relevant (translational) projects and it promotes the dissemination of best practices throughout the NM community in the country.

Our proposal for IFIN HH and ELI-NP would be to develop the Nuclear Medicine Activities around three different components:

a. **Research and Development** in radiochemistry and radiopharmacy.
b. **Radiopharmaceutical production**.
c. **Nuclear Medicine Clinic** facility to be created, should link with local community (hospitals, research at IFIN HH and ELI-NP and local authorities).

2. **What types of business models[2] would be appropriate for approaching when designing the NucMed Center and how could their implementation be done step by step? (3 business models feasible for the case of the NucMed are to be described)**

[1] A draft version of the resulted recommendations was presented by external experts to the activity's beneficiaries during a virtual meeting.

Several models are possible, from a fully public institution/NPO to a public/private partnership. In the case of the expert's home institutions (Coimbra and Kaposvar), the model is a fully public institution totally self-funded from radiopharmaceutical production, clinical scans and competitive R&D grants. Some other centers have mixed models between public and private institutions.

It is very important that in order for the Nuclear Medicine Clinic to be created the activities should not be separated. It means that the radiopharmaceutical production and medical investigations should be run in the same organization. The income from the routine radiopharmaceutical production and medical investigations should be used for research and development purposes.

3. **Which is the best approach for designing the NucMed Center: a) to build a new medical facility close to IFIN HH - ELI-NP? b) To create a distributed NucMed Center, a sort of virtual Center; IFIN HH & ELI-NP to be connected with the medical universities, main laboratories specialized in nuclear medicine, private entities from medical industry?**

The new facility we advise to be created is a Nuclear Medicine Clinic. This should be within the campus or in close proximity. A direct link with the production unit without crossing public area is essential to facilitate activities. The clinic should focus on diagnosis initially, but space should be left for future developments to include therapy (Theranostics). **Examples of similar centers and of good practice – reference point for the NucMed Center**

One example is ICNAS (Coimbra, Portugal), where it was build up a very busy and successful diagnostic centre, with radiopharmaceutical production for distribution, routine patient care and research and development. To their success it was necessary to have a strong research infrastructure and background and the commitment to the service for the community. Similar projects run in Hungary in Kaposvar, where a hospital runs a PET centre, who introduced 3 radiopharmaceuticals for patient care. The difference between the two centres is that, in Hungary, there is a very strict rule about production and utilization of (radio) pharmaceuticals. There is a very narrow list of indication where the PET/CT indications are reimbursed, and only radiopharmaceuticals with marketing authorization can be used. While in Portugal, as in the majority of European countries the local production and use of radiopharmaceuticals is legal.

[2] *These can cover a range of elements: business plans, examples of financial instruments for the development of the center, stakeholders involved, the risks generated by the financial instruments etc.

Sub-questions

a. What types of financial instruments could be accessed for this project?

The project requires significant funds which would be coming from the building costs (about 5 million euro) and equipment (similar amount). Since in Romania and in Bucharest there are several centres, there will be a strong competition.

b. What are the risks associated to those financial instruments and to the suggested business models?

If the public investment does not need to be returned, the centre is perfectly viable. The return expected from the activities (distribution of radiopharmaceuticals, clinical scans and research projects) can cover the running costs (maintenance contracts, consumables, utilities, salaries). A key component is the reimbursement of the PET scans. A good relation with national authorities is essential to ensuring that the main indications are covered.

c. What types of guarantee options are available for risk investments?

The current trends in the world show that nuclear medicine and especially PET are gaining momentum. For example, in Hungary with a population of 10 million people the quota for PET investigations raised from 12000 to 32000 per year in the last 7 years. Thus, there is room for new centres, and the risks are low for not getting back the investment.

5.2. Challenge 2 – Operation mode of the NucMed Center & technology transfer

Defining an operation mode for the Nuclear Medicine Center which aims to be constituted as a research center, where medical investigations can be done by doctors who will use new radio-isotopes developed by IFIN HH & ELI-NP.

Operation modes looked for should be based on already existing appropriate practice from Europe (i.e. like “core facilities”, open access tailored to different groups of users - doctors from nuclear medicine, top management of the Romanian medical universities. managers of hospitals, governmental agencies in medical field), other co-operation modes, currently state of the art that enable good business interaction or increased cooperation with researchers in the medical field (within the country and beyond borders).

The main questions addressed:

1. **How could the operation mode of the NucMed Center be organized** in a sustainable and feasible manner?

The focus should be on advanced studies not currently done by other centres. These studies would have a low cost of production and could be offered to the National Health Service, private hospitals and clinics and pharmaceutical industry (clinical trials) without disturbing the already existing market.

Time and resources should be shared 50/50 between clinical work and research to ensure a balanced level of activities. Rotation of users and applications would be of great help. For example, Mondays could be for Cardiology, Tuesdays to Wednesdays for Oncology, Thursday for Neurosciences and Friday for Paediatrics. This would help to optimize resources.

2. **How can access be offered to potential users**? (Doctors from all Romanian hospitals; Romanian patients; Patients from neighboring countries)

Potential users include patients, hospitals and clinics, other research centers and the pharmaceutical industry. Patients should be able to travel easily to the NMC for the scans. Public/private transport routes should be studied. As mentioned above, focus should be on advanced applications. Hospitals and clinics should be able to refer patients to the NMC. For some studies (e.g. cardiology/pediatric) the clinics could send their own doctors/nurses to accompany the studies.

3. **What kind of technology transfer strategies could be approached by the NucMed Center?**

Technology transfer could include new radiopharmaceuticals, new medical devices and new and improved protocols for clinical use. Those could be used by the NMC for its activities, could be licensed to other hospitals and clinics and could be offered as training for the national healthcare system thus helping to disseminate best practices.

4. **How can the offer to the market be organized and on what types of services should the Center focus on?**

As mentioned above, focus should be on advanced studies in Oncology, Cardiology and Neuroscience. The centre should be part of the clinical reference network of the National Health Service. Services should also be offered to private hospitals and clinics and the pharmaceutical industry. Services for other research centres should be consider under a pay-per-use approach.

5. **How should the propagation strategy look like? Starting from something smaller, how can the Center expand in the future? (through hospitals, universities, research centers etc.)**

The NMC should focus on diagnosis initially, but space should be left for future developments to include radionuclide therapy (Theranostics) and eventually protontherapy.

6. Final remarks

This pilot activity is not a formal review or evaluation, nor a comprehensive ex-ante assessment, but it was meant to help with triggering and steering the next steps needed in an

organization to progress with the preparations for the set-up of a research infrastructure or the development of internal co-ordination structures.

The involved team hopes that the recommendations mentioned above will serve to feed internal discussions within IFIN HH and ELI NP and will give a specific and informed feedback and support which will contribute to the efforts of designing/developing the desired Nuclear Medicine Center at IFIN HH / ELI NP.

Thus, we thank the representatives of IFIN HH and ELI NP for all the provided information, which contributed to the results of this pilot activity, as well as for the availability to host the on-site visit, and for facilitating the communication with relevant stakeholders.

7. Annexes

Annex no.1: Experts' working visit to IFIN-HH / ELI-NP

Day 1, Monday, the 6th of May, 2019

09:45 – 10:00 Coffee / Tea

10:00 – 10:30 Presentation of the ELI-NP Project and the connection with the nuclear medicine, Dr. Calin Ur, Technical Director of ELI-NP Project

10:30 – 11:00 Presentation of IFIN HH & ELI-NP research activity in the medical field, Dr. Mihai Radu, Scientific Director, IFIN HH, Dr. Dan Stutman, Coordinator, Research Area III, ELI-NP

11:00 – 11:15 Presentation of the NucMed project and of the activities already undertaken in this direction for a business model, Dragos Seuleanu, ELI-NP; MHTC, Executive Director

11:15 – 11:45 Portuguese experience in nuclear medicine, Dr. Antero J. Abrunhosa, Director of CNAS/University of Coimbra

11:45 – 12:15 Hungarian experience in nuclear medicine, Dr. Pál Mikecz, Medicopus Nonprofit Ltd./ Kaposi Mór Hospital, Kaposvár, Senior adviser

12:15 – 13:15 Break

13:15 – 14:00 Visit of the ELI-NP Facility

14:00 – 15:00 Meeting with representatives from the management of IFIN HH – ELI-NP and from different departments
Q&A session regarding the current operation structures of IFIN HH and ELI NP

15:00 – 15:30 Working session: Challenge 1 (from TOR) – ***Design and development of the NucMed Center & potential business models***

1. How can IFIN HH and ELI-NP capitalize in business on the scientific tradition, scientific results, and scientific future based on the most powerful laser in the world, so that it can create the proposed Nuclear Medicine Center?
2. What types of business models would be appropriate for approaching when designing the NucMed Center and how could their implementation be done step by step?
3. Which is the best approach for designing the NucMed Center: a) to build a new medical facility close to IFIN HH - ELI-NP? b) To create a distributed NucMed Center, a sort of virtual Center; IFIN HH & ELI-NP to be connected with the medical universities, main laboratories specialized in nuclear medicine, private entities from medical industry?
4. Examples of similar centers – reference point for the NucMed Center

15:45 – 17:15 Working session II: Challenge no.2 – ***Operation mode of the NucMed Center & technology transfer***

8. How could the operation mode of the NucMed Center be organized in a sustainable and feasible manner?
9. How can access be offered to potential users? (Doctors from all Romanian hospitals; Romanian patients; Patients from neighboring countries)
10. What kind of technology transfer strategies could be approached by the NucMed Center?
11. How can the offer to the market be organized and on what types of services should the Center focus on?
12. How should the propagation strategy look like? Starting from something smaller, how can the Center expand in the future? (through hospitals, universities, research centers etc.)

Day 2, Tuesday, the 7th of May, 2019

10:00 – 11:00 Visit to the Central Military Hospital, Bucharest

11:45 – 12:15 Working session - Recommendations regarding the development and operation of the NucMed Center

- **Challenge 1:** exploring **options of feasible and sustainable business models** for the Center
  recommendations and proposals for **specific actions** covering the short and mid-term perspective (up to 5 years)
- **Challenge 2**: suggestions and recommendations regarding the operation mode of the Center
  proposals for potential **technology transfer strategies**

proposals for **practical tools** to develop a functional relation with external stakeholders & potential users

12:15 – 13:00 Conclusions and next steps

- Deliverables of the Pilot Activity
- Upcoming Know-How Exchange Forum in Bratislava

Location: Str. Reactorului no.30, Bucharest - Magurele, Romania

Annex no.2: Terms of Reference Call for single experts or expert teams to participate in a ResInfra@DR support activity – Support in designing/ developing of the Nuclear Medicine Center at the Horia Hulubei National Institute for Physics and Nuclear Engineering

Annex no.3: ResInfra@DR call for Expressions of Interest addressed to research organisations, research infrastructures and their parent organisations

Interreg
EUROPEAN UNION
Danube Transnational Programme
ResInfra@DR

ToR call for
single experts or expert teams

to participate in a ResInfra@DR support activity

Support in designing/developing of the Nuclear Medicine Center at the Horia Hulubei National Institute for Physics and Nuclear Engineering

Terms of References

Project co-funded by European Union funds (ERDF, IPA). http://www.interreg-danube.eu/resinfra-dr

BACKGROUND and PURPOSE

The ResInfra@DR project is designed to strengthen Research Infrastructures (RI) in the Danube macro-region (DR) and runs from January 2017 to June 2019. The project is co-funded by European Union funds (ERDF, IPA).

The main activities of the ResInfra@DR project include:

- a dialogue focusing on relevant regional, national and macro regional but also EU level policy fields involving also end-users of RIs;
- special trainings for defined target groups, thus contributing to capacity building with an outreach to the entire macro-region and beyond the partnership involved;
- a collection of a dataset of competent and qualified reviewers for RI assessments;
- **two pilot activities focusing on**
  (a) peer actions including existing RIs (pilot activity 1)**;**
  (b) **Ex-ante support of planned or planned to be upgraded RIs in countries of the Danube macro region (pilot activity 2 and subject of this ToR);**
- the dedicated dissemination and capitalization actions contribute to the policy take up and utilization of the results.

The present call concerns the second pilot activity (b), "Ex-ante support to planned or to be upgraded RIs in the Danube macro-region".

The core element of this support action will consist of specific **recommendations provided by an expert team** that will work together with the ResInfra@DR partnership.
Teams will consist of **two external experts who are identified with the help of this ToRs** and will be supported by further ResInfra@DR partner team members.

SPECIFIC SUPPORT REQUESTED

Support in designing/developing of the Nuclear Medicine Center (NucMed Center) **at the Horia Hulubei National Institute for Physics and Nuclear Engineering**

Horia Hulubei National Institute for Physics and Nuclear Engineering (IFIN HH) and the Extreme Light Infrastructure - Nuclear Physics Project (ELI-NP) want to capitalize from their scientific results in the field of nuclear physics and extreme light infrastructure in relation to the medical community in order to generate a N**ucM**ed Center.

In this context, the core idea is to design the NucMed Center and to encourage the development of joint research projects between the governmental agencies in the medical field, the Romanian medical universities and hospitals with nuclear medicine activity.

The NucMed Center should promote the nuclear medicine applications, based on the research expertise from IFIN-HH to the medical community and industry and end-users.
Because the concept of creating the NucMed Center is at a really early stage, IFIN HH looks for specific guidance and support during this current preparation phase of this planned research center which is strongly related to its existing research infrastructures.

The experts will need to identify the current phase of design and make suggestions and recommendations on the activities to be done in order to develop the NucMed Center.

The NucMed Center should function as a core research center for medical investigations done by doctors who will use new radio-isotopes developed by IFIN HH and ELI-NP.
It is expected for its offer to consist of:

- Production of Radioisotopes/radiopharmaceutics for diagnostic and therapy medical applications.
- Validation of new radiopharmaceutics (this activity is the IFIN HH & ELI-NP's responsibility)
- Design and validation of new radiopharmaceutics (synthesis, participation in preclinical and clinical evaluation research)
- Preclinical and clinical research will be done together by the IFIN HH & ELI-NP and doctors & professors from medical universities.

Regarding their offer on the market, the radiopharmaceutics intended to be produced by the IFIN HH and ELI-NP (to be used in Romanian nuclear medicine clinics) are already available on the international market. In this respect IFIN HH and ELI-NP through NucMed Center wish to become a local supplier for the national market.
This center should be developed in partnership with medical universities from all over the country, hospitals, public authorities and the private sector. It should be organized as a public organization or as an organization based on a public-private partnership, for profit. From a business point of view, IFIN HH and ELI-NP will be the catalyst for NucMed Center. IFIN HH and ELI-NP will be the provider for the nuclear material necessary for the medical analyzes and treatment. The patients will pay the services.

Regarding the technology transfer, Magurele High Tech Cluster will be in charge. Members of the Cluster and NucMed Center will be the beneficiaries.

There are three main target groups for the NucMed Center: doctors from all Romanian hospitals; Romanian patients and patients from neighboring countries.

The IFIN HH has sent a request to ResInfra@DR, the addressed questions were clarified in advance to this ToR call by the partners of ResInfra@DR.

A list of specific challenges and questions has been identified to specify the support seeked from experts within this call.

The **core topics of interest** identified are presented in the following table:

Challenge	Description of challenge and core questions*	Expert recommendations requested
Design and development of the Nuclear Medicine Center at ELI NP & IFIN HH ⇨ & business models	The IFIN HH and ELI-NP proposal for the planned research infrastructure - the NucMed Center is at the very early stage of design. Their main challenge is related to the creation of the Nuclear Medicine Center (how to create it, what are the main steps and activities, what form should it have, examples of business models). The main questions that need to be addressed by the experts in this regard are the following: 1. How can IFIN HH and ELI-NP **capitalize in business** on the scientific tradition, scientific results, and brilliant scientific future based on the most powerful laser in the world, so that it can create the proposed Nuclear Medicine Center? 2. What types of **business models** would be appropriate for approaching when designing the NucMed Center[1] and how could their implementation be done step by step? 3. Which is the best approach for designing the NucMed Center: a) to build a new medical facility close to IFIN HH - ELI-NP? b) To create a distributed NucMed Center, a sort of virtual Center; IFIN HH & ELI-NP to be connected with the medical universities, main laboratories specialized in nuclear medicine, private entities from medical industry? **Sub-questions** • What types of financial instruments could be accessed for this project? • What are the risks associated to those financial instruments and to the suggested business models? • What types of guarantee options are available for risk investments?	The IFIN HH and ELI-NP look for recommendations and suggestions regarding the development and design of the NucMed Center and its functions and organization. Experts should analyze the current operation structures of the IFIN HH and ELI-NP and propose solutions for the creation and integration of the Nuclear Medicine Center. Experts should put emphasis on how IFIN HH and ELI-NP may **capitalize from the scientific results of ELI NP** in relation to the medical community in order to generate a NucMed Center. The experts should also provide information on **similar centers**, if any, that can be taken as a reference point for the development of the NucMed Center. The experts are required to recommend **3 examples of feasible and sustainable business models** for the Nuclear Medicine Center. *These can cover a range of elements: business plans, examples of financial instruments for the development of the center, stakeholders involved, the risks generated by the financial instruments etc. Following a **stepwise approach**, recommendations and proposals for specific actions should cover the short term and midterm perspective (the coming 5 years) – similar to a Roadmap.

Challenge	Description of challenge and	Expert recommendations requested

1 In the situation in which, the NucMed Center will be an organization for profit, public or based on a public-private partnership.

	core questions*	
Operation mode of the Nuclear Medicine Center ⇨ & technology transfer	Defining an operation mode for the Nuclear Medicine Center which aims to be constituted as a research center, where medical investigations can be done by doctors who will use new radio-isotopes developed by IFIN HH & EL-NP. Operation modes looked for should be based on already existing appropriate practice from Europe (i.e. like "core facilities", open access tailored to different groups of users - doctors from nuclear medicine, top management of the Romanian medical universities. managers of hospitals, governmental agencies in medical field), other co-operation modes, currently state of the art that enable good business interaction or increased cooperation with researchers in the medical field (within the country and beyond borders). The related questions are: 1. How could the **operation mode** of the NucMed Center be organized in a sustainable and feasible manner? 2. How can **access** be offered to potential users? (Doctors from all Romanian hospitals; Romanian patients; Patients from neighboring countries) 3. What kind of **technology transfer strategies** could be approached by the NucMed Center? 4. How can the **offer to the market** be organized and on what types of services should the Center focus on? 5. How should the **propagation strategy** look like? Starting from something smaller, how can the Center expand in the future? (through hospitals, universities, research centers etc.)	Recommendations could include proposals regarding the **best approach for the operation** of the Nuclear Medicine Center and the activities/steps that can be undertaken. All types of alternative solutions are highly welcome to contribute to a tailor made operation mode. The experts should also provide information on **similar centers**, if any, that can be taken as a best practice for the operation of the NucMed Center. Following a **stepwise approach**, recommendations and proposals for specific actions should cover the short term and midterm perspective (the coming 5 years) – Experts are expected to provide: - suggestions and recommendations regarding the operation mode of the NucMed Center; - suggestions and proposals for practical tools to develop a functional relation with external stakeholders and potential users; - proposals regarding potential technology transfer strategies.

*Applicants should inform in which field they can contribute best and which questions they cannot easily answer. In case of single experts the ResInfra@DR project will try to match the expertise of the expert with other applicants to cover if possible most of the questions addressed.

Overall, the IFIN HH looks for recommendations that propose important steps or activities that contribute to the creation and development of theNuclear Medicine Center. The expert opinion and suggested activities are considered as important for the necessary set up of the structure and operation principles of the Nuclear Medicine Center in a short and mid-term perspective. IFIN HH is aware that the recommendations which will be received are expert opinions and recommendations.

Expert contributions and findings should follow a critical friend approach and do not follow a specified set of criteria as the action is not considered an evaluation. This approach shall allow to provide context related knowledge to the IFIN HH leadership.

This ToR call tries to identify experts or expert teams.

This call can be answered either by single experts or expert teams consisting of two experts.

- Teams of experts should hand in jointly their documents. It is necessary that teams demonstrate the complementarity of their expert knowledge.
- In case of single experts the ResInfra@DR project will try to match the expertise of the expert with other applicants to cover if possible most of the questions addressed.

Please find more technical details on the application later in the document on the following pages!

Experts are invited to contribute by:

- interacting with the IFIN HH and ELI-NP during virtual meeting(s) to clarify open questions concerning the expectations and questions; setting up a schedule for the 1-1.5 days visit;
- participating as experts in the 1-1.5 days visit and all its specific sessions, a reflection meeting on site (travel No1)[2];
- drafting the core parts of the recommendations including field specific examples to showcase good practice (the length of this document is not specified);
- present the recommendations findings on site (travel No2)[3] or during online meetings;
- support the identification of general experiences made during the exercise to advise similar actions in future and draft some core points that should be taken on in future (learning results from the action).

[2] Costs for Travel No1 including the 1-1.5 days on site visit are included in the expert fee and need to be arranged after joint agreement with the included team members.

[3] Travel No2 or further travels will be arranged directly by the financing partner and will be covered by an additional contract only covering the travel and accommodation costs but no daily fee/allowance can be covered.

IFIN HH and ELI NP as the final beneficiary of the organized support action will:

- inform the experts before their visit on site about the current situation, the planned visit schedule by use of documents, provision of information during virtual meetings, skype calls etc.;
- identify the relevant persons and stakeholders in Romania (and beyond where relevant) which can provide further input in the specific field;
- prepare the necessary schedule for (3-5) meetings with stakeholders for a 1 or 1.5 day visit of experts and will agree with stakeholders on their participation in the necessary meetings;
- host and organize the necessary meetings with concerned stakeholders in the country;
- organize a meeting venue for the expert team to prepare recommendations and reflect on first findings of the days of the visits;
- welcome for a follow up visit (if necessary) the experts and team members of ResInfra@DR in order to discuss the developed recommendations and most important, to facilitate the internal process by informing the relevant stakeholders;
- participate at the planned ResInfra@DR learning event planned to be held in May 2019 in Romania.

Role of the ResInfra@DR team member/s:

The contracting ResInfra@DR partner is the core addressee for clarifications in the team, but the responsibility for its functioning is shared with the further ResInfra@DR team members. The project ResInfra@DR team members (partners of ResInfra@DR) involved support the action by:

- identification of the above listed topics in a dialogue with IFIN HH and ELI NP (preparation of this ToR call); publishing the ToRs and sending the ToRs document to relevant experts to invite and ask for their participation;
- collecting replies to this ToR call and selecting together with IFIN HH and ELI NP the best fitting experts;
- contracting of external experts and processing the necessary payments;
- organizing the confidentiality agreements;
- organizing virtual meetings to prepare the visit of experts to Romania, interacting with IFIN HH to facilitate the structure of the 1-1.5 days working visit;
- presence during the 1-1.5 days meetings to ensure best focus of the action (one/two ResInfra@DR team members can participate);
- contributing to the recommendations drafting process, its writing and presentation when necessary and in case it can add up to the expert recommendations, organizing agreed virtual meetings etc;
- supporting the presentation in Romania, if possible together with expert(s).

Confidentiality:

Involved team members (external experts, ResInfra@DR team members) will sign a confidentially agreement with the IFIN HH. While the content of the prepared documents is to be kept generally confidential, agreed parts should be made available by IFIN HH for cost documentation of experts work, for sharing of the experiences made during the pilot exercise within ResInfra@DR. IFIN HH also provides the necessary background documents to enable the work of experts and the involved teams.

Time frame

The following timeframe applies to the action and expert involvement

- Information of possible experts about their interest to participate (opening of the ToR call and date of announcement) 06 March 2019
- Deadline for applications: 18 March 2019
- Selection procedure concluded and date of contracting completed - March 2019
- Visits (Travel 1) should be organised in April 2019
- The action should end in May 2019

Selection of experts

Applications from teams of experts (two complementary experts) are highly welcome, in case of applications of single applicants two experts will be paired to form a team.

Expressions of Interest/Applications received will be screened by the ResInfra@DR partnership, the following selection criteria applies:

- Demonstrated experience in the specific field of nuclear medicine, radio pharmacy, molecular imaging, radioisotopes (20 points)
- Demonstrated experience in business in the field of science (10 points)
- Knowledge about research infrastructure processes (10 points)
- Reply to the questions and core points (10 points)
- Description of risks of the exercise (5 points)
- Cost plan (not exceeding 3000€ per expert including travel 1) (5 points)

Expert teams will be assessed separately from single applications to ensure fairness in the process.

Funding of the action and contracting of the partners

The cost coverage for a single expert cannot exceed 3,000€ which includes the costs for one trip to Romania (Travel 1 to be covered from the amount). Coverage means that travel costs and accommodation costs are included.

In case of expert teams, both experts shall participate in the on-site 1-1.5 days trip (Travel 1), the expert fee per expert can not exceed 3,000€ (in total not exceeding 6,000€ for the team).

In case of teams of experts, each will receive a separate contract.

The contracts with experts will be concluded with the Romanian partner in ResInfra@DR (contact details below).

Application procedure and necessary documents:

The qualifications of the experts who will contribute to the above tasks shall be demonstrated through:

- a **cover letter/e-mail** with short description of the motivation and provision of contact details, also informing about the team members in case a team of experts applies jointly (not exceeding half a page). Note that expert teams need to provide this document only once;
- a **CV,** highlighting relevant experience and reference projects or activities (not limited to scientific tasks). Teams need to provide a CV for both experts;
- taking on the list of questions raised, **a max. 2 A4 page "considerations of questions"** document should inform about core points/issues which are considered as important for the addressed issues. This can also contain references to other developments, operation models, relevant standards etc. which are of interest for the specific case of IFIN HH. Note that expert teams need to provide this document only once.
- on a single A4 page document (a) an assessment of the risks of the exercise; (b) a cost plan including the consultancy days provided. Note that expert teams need to provide this document only once.
- in case the applicant will not be available for more than 3 weeks in the upcoming 2 3-month period, he/she should **provide information** with the application (start and end date of the period when the expert will not be available). Note that expert teams need to provide this document only once.

The documents for the response to this ToR call (not exceeding 10 MByte) must be sent by e-mail to: resinfra.pilot@zsi.at

Contacts for further information

In the case of questions, interested entities can contact the ResInfra@DR partners for further information.

Austria:
ZSI-Zentrum für Soziale Innovation GmbH (Centre for Social Innovation)
Linke Wienzeile 246, A-1150 Vienna, Austria
Person in charge of the project: DI Martin Felix Gajdusek, Phone: +43-1-4950442-67
e-mail: gajdusek@zsi.at (resinfra.pilot@zsi.at)

Romania:
Executive Agency for Higher Education, Research, Development and Innovation Funding, Academiei street, no. 39-41, Bucharest, 010013
Persons in charge of the project: Raluca Ciobotaru
e-mail: raluca.ciobotaru@uefiscdi.ro

General information on the Pilot action

The expected OUTPUTS of the action and including all contributing parties

(1) **The first core result and output of the pilot action is a recommendation document which** will include expert opinions and recommendations including recent examples of how the challenges can be met; or elements of roadmaps to show the development options and what could be achieved over time in a stepwise approach; thematic (scientific) expert opinions that take on the challenges in the specific field.

This document should give guidance to IFIN HH how it could further develop its research infrastructure activities.

The following stepwise approach is followed:

- A **recommendations draft document** is developed in a first step by the whole team, this is based on the following information:
  - on information received from the IFIN HH; could be previous activity reports or assessments; information received in person during the preparatory exchange round in online meetings or by sending documents etc.
  - specific information received during the 1-1.5 days visits which include also meetings with stakeholders on site (IFIN HH and ELI NP representatives and other relevant stakeholders for this pilot activity);
  - a reflection round of the whole team on site during the visits.
- The recommendation draft document is prepared by the team and will be presented afterwards to IFIN HH in a virtual meeting to allow a revision and correction of yet unclear parts.
- After a revison round by the team at this stage a **confidential full set of recommendations** will be available for the IFIN HH.
- In a next step the IFIN HH will agree with the expert team on a **publishable and non-confidential version of the recommendations**.
- **A presentation of the results** during a visit (travel 2) will be organised on site in Romania, confidential parts of the recommendations (parts which should be kept internal) need to be agreed in advance. ResInfra@DR partners will be present and in case of necessity also expert/s can participate. (The financing partner needs to cover directly travel and accommodation costs as they are not covered in the expert contracts subject of the present ToR call).
- A **concluding report based on the publishable and non-confidential version of the recommendations** will be prepared which is a formal deliverable of the Resinfra@DR project and represents the documentation of the whole Pilot action conducted in Romania.

(2) The **second element of the action** consists of a reflection that finally should help to identify what can be learned from the process for similar actions in future and also beyond the specific field covered in the pilot action. A certain focus on the Danube Macro-region should be maintained. Note that expert contribution is only partly necessary but highly welcome.

This reflection might include exemplary the following elements:

*(1) Critical **success factors** for similar support actions based on peers putting the "critical friends approach" in the center of support;*
*(2) **Shortcomings** of the approach (subjective approach, limited resources and timeframe, uptake of results etc.*
*(3) What would make the **approach better**;*
*(4) What **other approaches** can be suggested to reflect the limits of the action;*
*(5) What could be suggestions for developing such actions further in the **Danube macro-region;***
*(6) **Other** issues which are of importance.*

The following stepwise approach is followed:

- During the action the transferability of the approach should be reflected also when drafting the recommendations or during the visit; here also experts can contribute accordingly;
- The already concluded process will be reflected in a **dedicated virtual meeting** or in bilateral communication i.e. by using the above list or adding more points, the presence of experts is encouraged;
- The involved ResInfra@DR partners should draft a 2-3 pages input which is collected from other parallel running peer actions in other countries, the experts can provide further feedback, as well IFIN HH should use its own viewpoint to contribute;
- ResInfra@DR collects the input from all parallel running actions to prepare a **draft deliverable on learning results from this pilot activity** taking up the findings from the actions.
- A **mutual learning event** will take place in **Slovakia** in May 2019 (travel 3) and all parallel running actions will be presented by the ResInfra@DR partners involved and also IFIN HH should participate to show its viewpoint. Upon interest of experts they will be invited.
- Especially involved actors i.e. the IFIN HH and the team involved in research infrastructure planning will be invited by the organizers (cost coverage planned). Note that at the moment of this ToR call the concept of this meeting is not available.).

(3) Note that this action is **not a formal review or evaluation, nor a comprehensive ex-ante assessment** but it can help with triggering and steering the next steps needed in an organization to progress with the preparations for the set up of a research infrastructure or the development of internal co-ordination structures.

(4) **Confidentiality:** an **agreement on disclosure of information** will be signed to ensure confidentiality throughout the process. Confidentiality declarations on the disclosure of information will be signed by all included experts. Only explicitly agreed parts (formally approved by participating organisations) will be shared.

Interreg
EUROPEAN UNION
Danube Transnational Programme
ResInfra@DR

Pilot Actions

LOT 1

ResInfra@DR call for Expressions of Interest

to participate in a ResInfra@DR support activity
addressed to research organisations, ministries and agencies

- planning, developing and upgrading research infrastructures;
- establishing research infrastructure networks; widening the participation in networked research infrastructures

ADDRESSED TO RESEARCH ORGANISATIONS, RESEARCH INFRASTRUCTURES AND THEIR PARENT ORGANISATIONS

ResInfra@DR - Pilot Activity 2 within the project ResInfra@DR

Project co-funded by European Union funds (ERDF, IPA). http://www.interreg-danube.eu/resinfra-dr

BACKGROUND

The ResInfra@DR project is designed to strengthen Research Infrastructures (RI) in the Danube macro-region (DR) and runs from January 2017 to June 2019. The project is co-funded by European Union funds (ERDF, IPA).

The main activities of the ResInfra@DR project include:

- a dialogue focusing on relevant regional, national and macro regional but also EU level policy fields involving also end-users of RIs;
- special trainings for defined target groups, thus contributing to capacity building with an outreach to the entire macro-region and beyond the partnership involved;
- a collection of a dataset of competent and qualified reviewers for RI assessments;
- **two pilot activities focusing on**
  - (a) peer actions including nine existing RIs (pilot activity 1, not subject of this ToR);
  - **(b) LOT 1 Ex-ante support of three planned or to be upgraded RIs in countries of the Danube macro region (pilot activity 2 und subject of this ToR);**
- the dedicated dissemination and capitalisation actions contribute to the policy take up and utilisation of the results.

The present call concerns the second pilot activity, "Ex-ante support to three planned or to be upgraded RIs in the macro region".
The second pilot activity puts a focus

(a) on existing or future support measures resp. funding schemes which are/will be supporting RIs. (NOT subject of LOT 1 of this EoI call)
(b) on planned research infrastructures where substantial parts already exist including planned networked RIs; (subject of LOT1 of this EoI call)
(c) the further development or the envisaged upgrading of existing research infrastructures including networked RIs; (subject of LOT1 of this EoI call).

This LOT1 call addresses the research organisations planning or upgrading their RIs or networked RIs, parent organisations involved in such process but also ministries and agencies involved in the planning or upgrading of RIs.
Especially encouraged are organisations that already operate parts of a research infrastructure and look for furhter development.

Throughout the activity, entities responding to this Expressions of Interest (EoI) call will receive **recommendations and expert opinions free of charge**. Expert fees and travel costs will be covered by ResInfra@DR.

PURPOSE

The main **purpose of this call LOT1 for EoIs** is to identify **interested research entities or parent organisations of RIs** wishing to participate in the **pilot activity focusing on Research Infrastructures in the Danube macro-region**. Received EoIs will enable the local partners of ResInfra@DR to define useful support actions in a dialogue process together with the interested parties.

The core element of this support action will consist of specific **recommendations provided by an expert team** that will work together with the ResInfra@DR partnership. Teams have to be set up according to the questions addressed and will consist of external experts who can be identified and selected on a case by case basis and of ResInfra@DR partners. After reaching an agreement regarding the profiles of the necessary experts, ResInfra@DR will launch a separate call for experts.

During this highly cooperative process of experts working with the interested applicants, different kind of meetings can also be organized, such as: dialogue meetings, workshops, individual meetings with important stakeholders. The provision of relevant information to the expert team from the side of the entities involved is necessary in order to enable appropriate footing of the developed recommendations.

This EoI addresses **research organisations planning or upgrading their RIs or networked RIs, their parent organisations and where relevant ministries and agencies involved in the planning or upgrading of RIs** who are looking to progress in their current preparation processes; to find new solutions for future operation, to establish new approaches for their own management e.g.

- for preparatory steps of RIs where a substantial part exists already i.e to develope a realistic vision, internal strategy or a roadmap for their further development; other steps can be supported as well;
- for the upgrading of existing Ris, specific solutions sought might concern e.g. the required HR capacities of the operating team; the user access and its management; monitoring challenges on the expected operation; other pressing questions related to the management of an RI;
- for networked infrastructures including RIs new solutions might be desired e.g. for the equality of network nodes; the establishment of new nodes, the balanced use by incoming researchers; maximising the follow up cooperation with hosted users; other pressing questions.
- for joining existing RI networks on macro regional, European or global scale - specific questions arise that e.g. concern the benefit of the national research community; relevance of participation in RI networks; other pressing issues.
- This EoI call **does not** provide assistance for the establishment of research infrastructures where no substantial parts of a RI exist or networks of RIs where not at least one RI in one of the sites already exists. This EoI call does not provide assessments for a specific investment in specific RIs which are regularly received by funders or the relevant ministries.

The core topics that will be covered through this exercise were listed above and can be further developed in accordance to the specificities of the EoI call applicant. Moreover, the exact focus needs to be defined in a further step together with the ResInfra@DR partners, on a case to case basis.

This EoI invitation is directed at[1]:

- **Research organisations** planning or upgrading their RIs or networked RIs, parent organisations of RIs, ministries and agencies involved in the planning or upgrading of RIs.
- **Research organisations** considering
    - the establishment of a research infrastructure where a substantial basis already exists i.e. in an existing laboratory;
    - the upgrading of an existing research infrastructure;
    - the involvement in an existing research infrastructure network;
    - specific actions which involve Danube Region countries as part of their RI activities.

- **National authorities such as ministries and agencies** in charge of research infrastructures from the Danube macro-region ecpecially those who act as parent organisations of RIs
- **Macro-regional active networks** who intend to establish or upgrade geographically dislocated research infrastructures and who want to focus on one or more of the countries/regions to promote their involvement are welcome to submit an application as long as the EoI request is handed in from the above mentioned organisations.
- This invitation also addresses **ResInfra@DR partners** which can respond to the EoI on an equal base.
- Note that only entities from **countries part of the Danube macro region** can apply to this EoI, an exception would be the case where an initiative would be created outside of the DR but the main benefit will occur in the Danube region. Applications are welcome for the EoI request as long as they are handed in from the above mentioned organisations.

This specific EoI does not addres funders or Research funding agencies who look to develop their funding programmes, in such case LOT2 of the EoI call can provide support.

[1] Typical initiatives of research infrastructures (RIs) include equipment, facilities or (virtual) platforms, material repositories, data repositories, information systems and services, which are indispensable for scientific research activities and for the dissemination of the results. RIs can be single-sited or distributed, can be an e-infrastructure, and can be part of a national or international network of facilities, or of interconnected scientific instrument networks.

FURTHER STEPS

- **Further process and outputs:** EoIs received will be screened by the ResInfra@DR partnership on how well they fit the purpose of the action along pre-defined criteria (see below). Based on the EoIs received, the partnership will start a dialogue with the selected applicants to specify core fields where the expert teams can offer support realistically and with a strong focus on the support needs.
- **ResInfra@DR partners and selected Experts** will form a team and will clarify through dialogue which are the relevant goals and the types of support that can be realistically achieved. During exchange meetings, the workmode should be defined jointly in order to maximize the applicability of results by the selected applicants.
- **The support offered** will include expert opinions and recommendations; elements of roadmaps; when necessary, thematic (scientific) expert opinions; dialogue meetings with stakeholders within or outside of the applicant's country (depending on the specificities of the case). During the first stage, a **confidential full set of recommendations** will be available for the selected applicant and the involved stakeholders. Secondly, participating organisations will jointly agree with the expert team on a **publishable and non-confidential version of the recommendations**. Finally, a concluding report based on agreed and publishable parts will be prepared and presented after agreement. In order to safeguard the information received, confidentiality declarations on the disclosure of information will be signed with all included experts.
- A core element of the action will consist of a process of **mutual learning** for the involved actors (research entities, parent organisations of RIs, or other types of selected applicants), and the team involved in planning. Therefore involved actors will be invited to **a mutual learning meeting** (including both pilot activities).
- Note that this is not a formal review or evaluation, neither a full ex-ante assessment but it can help withtriggering and steeringn the next steps needed in order to progress with the preparations.
- ResInfra@DR will **support at least three planned RI-related initiatives,** but based on the number of EoIs received and the type of necessary support expected, this number could also be increased.
- **Financial conditions:** The offered support by the ResInfra@DR project will be **free of charge** and the process and products including the recommendations established will be **freely available for the participating organisations** and **no dedicated payment** from or to the participating organisations is envisaged. The nececessary expert fees for selected thematic experts, costs of meetings and travels will be covered by ResInfra@DR.
- **Confidentiality:** The organisations answering this EoI should be aware that a certain **sharing of information** is necessary, an **agreement on disclosure of information** will be signed to ensure confidentiality throughout the process. Confidentiality declarations on the disclosure of information will be signed with

all included experts. Only explicitly agreed parts (formally approved by the participating organisations) will be shared.

- **Timing:** Note that the support takes place **till the end of January 2019**. For any further clarifications, please do not hesitate to contact one of the partners listed below.

RESPONSE AND EXPRESSION OF INTEREST

Expressions of Interest (EoIs) are sent in written and shall include 4 elements (content is kept confidential):

1. A maximum of in total 3 pages of information containing the following elements::
    - Type, background of the specific RI and the concerned initiative;
    - Information on the core stakeholders or actors involved in the process.This can also include links where information can be found;
    - Overview (can also include data) about the current situation and of the planned steps where available;
    - Stage of development in the planning - which steps have already been concluded, what is planned further;
    - Current challenges and related questions which could potentially be addressed to an expert team, including questions for which answers are sought (note that questions on financing are **not** a core point).
    - Adding questions where you currently search for solutions are important to clarify the support which can be offered realistically.
    - Where applicable, information on the strategic relevance for the Danube macro region;
    - Names of expert(s) you would suggest as potential team members of the expert team offering recommendations and support (this is not mandatory, and their inclusion in the expert team will be reviewed in accordance with the purpose of the Action).
2. A letter from the organisation informing about the general interest to participate can be added, such letter can be also added at a later stage.
3. Contact details including e-mail and phone.
4. Information on availability during October to start a clarification process.

The above points 1-4 should be prepared in English language and should be sent to: resinfra.pilot@zsi.at

TIMEFRAME

- Announcement of the call: 1 October 2018
- **EoI submission deadline: 15 October 2018 12:00 CET**
- The received EoIs will be screened by the ResInfra@DR partners. The local ResInfra@DR partners will approach the EoI applicants for further clarification

(depending on availability). A final decision on the support will be made after further clarification within the partnership.

- As a further step, **a joint meeting of the interested organisations will be organised in November 2018** (potentially in Belgrade, Budapest, Prague or Vienna).

CRITERIA

Priority criteria for inclusion in the Pilot action to be used by the ResInfra@DR partnership for the EoIs are:

- Interest and motivation of the proposer/the EoI applicant including also the internal backing of the plans;
- Feasibility of the support i.e. specific and realistic questions which the team consisiting of ResInfra@DR partners and external experts can indeed provide answers for;
- Relevance for region(s) and countries of the EUSDR or further integration in european developments and integration i.e. concerning the participation in EU wide activities.

Given the complexity and the diversity of the potential applicants and EoIs received, a more precise selection criteria cannot be provided at this stage**.**

CONTACTS FOR FURTHER INFORMATION

In the case of questions, interested entities can contact the ResInfra@DR partners for further information. Once an EoI will be taken on as part of the Pilot activity 2, the corresponding partner will also support the process.

Austria:
ZSI-Zentrum für Soziale Innovation GmbH (Centre for Social Innovation), Lead partner
Linke Wienzeile 246, 1150 Vienna, Austria
DI Martin Felix Gajdusek, Phone: +43-1-4950442-67 e-mail: gajdusek@zsi.at

University of Natural Resources and Life Sciences, Vienna
Institute of Water Management, Hydrology and Hydraulic engineering (at the Department for Water-Atmosphere-Environment)
Address: Muthgasse 107, A-1190 Vienna, Austria
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Bosnia and Herzegovina:
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Countries part of the Danube macro-region for which no dedicated contact is identified: (Germany (Bayern, B-W only), Montenegro, Slovenia, Ukraine only oblasts included in DR) will be arranged on a case by case basis, here the following organisation can be approached:

ZSI-Zentrum für Soziale Innovation GmbH (Centre for Social Innovation), Lead partner
Linke Wienzeile 246, 1150 Vienna, Austria
DI Martin Felix Gajdusek, Phone: +43-1-4950442-67 e-mail: gajdusek@zsi.at

The ZSI will organise also the documentation of the EoI call

The document for the response to this EoI (not exceeding 10 MByte) must be sent by e-mail to: resinfra.pilot@zsi.at