



**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

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 **NucMed 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 sought 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
<p>Design and development of the Nuclear Medicine Center at ELI NP & IFIN HH ⇒ & business models</p>	<p>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).</p> <p>The main questions that need to be addressed by the experts in this regard are the following:</p> <ol style="list-style-type: none"> 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 Center¹ 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? <p>Sub-questions</p> <ul style="list-style-type: none"> • 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? 	<p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>The experts are required to recommend 3 examples of feasible and sustainable business models for the Nuclear Medicine Center.</p> <p>*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.</p> <p>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.</p>

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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*	
<p>Operation mode of the Nuclear Medicine Center ⇒ & technology transfer</p>	<p>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.</p> <p>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).</p> <p>The related questions are:</p> <ol style="list-style-type: none"> 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.) 	<p>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.</p> <p>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.</p> <p>Following a stepwise approach, recommendations and proposals for specific actions should cover the short term and midterm perspective (the coming 5 years) –</p> <p>Experts are expected to provide:</p> <ul style="list-style-type: none"> - 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 the Nuclear 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 confidentiality 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 revision 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.