

## **Is there a business model for medical applications from ELI-NP advanced research?**

### **Extreme Light for a Better Life – Nuclear Medicine Center (NucMed)**

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### **Background of the specific Research Infrastructure and of the proposal**

#### 1. International background

“In Finland (population 5.3 millions) there are five university hospitals with full nuclear medicine services, all of which are equipped with PET/CT. One of the leading European radiopharmaceutical companies, MAP Medical Technologies Oy, has three production sites in Finland, so the access to the radiopharmaceuticals is good in spite of long distances within the country. There is nuclear medicine activity in approximately 40 laboratories in Finland. The cyclotron facilities for radiopharmaceutical production are located in Turku and Helsinki.[ ] Kalevi Kairemo, World Journal of Nuclear Medicine, Nuclear Medicine in Finland, 2012, Volume 11, page: 101-102, <http://www.wjnm.org/article.asp?issn=1450-1147;year=2012;volume=11;issue=3;spage=101;epage=102;aulast=Kairemo> .

IFIN-HH is the largest research institute in Romania having the most significant research results. The Institute developed during the years three departments that included in their scope of activity fields of life sciences: Department of Life and Environment Physics, Department of Radioisotopes and Radiation Metrology, Department of Technological Irradiation. There are, also, a number of interdepartmental interactions involving other research groups: the TANDEM Accelerator Department, the Radiopharmaceutical Research Center, the Radiology Metrology Group, the Department of Computational Physics and Information Technologies, the Department of Applied Nuclear Physics). The Radiopharmaceutical Research Center produces some radiolabeled compounds useful in imaging and local radiotherapy, an application being in preparation for a license to delivery some of these radiopharmaceuticals to clinics.

**The Radiopharmaceuticals Research Centre (CCR: <http://ccr.nipne.ro/> )** - a complex system comprising a versatile cyclotron, radiochemistry and analytical laboratories, automated synthesis units, and a micro PET, represents a state of the art experimental facility, dedicated to research in the fields of radiochemistry, radio pharmacy and nuclear physics applications, facilitating a modern and efficient application of nuclear technology in life sciences. The CCR Research Programme addresses significant topics such as interdisciplinary basic research in physics, biology, chemistry, applied research towards clinical applications of novel radiopharmaceuticals for medical imaging and targeted radiotherapy as well as the development of new pharmaceuticals.

“Extreme Light Infrastructure (ELI) will be the only European and International Centre for high-level research on ultra-high intensity laser, laser-matter interaction and secondary sources with unparalleled possibilities. Its pulse peak power and briefness will go beyond the current state-of-the-art by several orders of magnitude. Because of its unique properties, this multidisciplinary facility will provide magnificent new opportunities to study the fundamental processes unfolded during light-matter interaction. ELI will create a platform, where Extreme Light applications for the benefit of society will be dynamically promoted.

In its mission ELI will practice a vigorous technology transfer to European SMEs and large firms. High on ELI agenda will be the training of aspiring scientists and engineers in the numerous disciplines associated with the Extreme Light. The ELI project, a collaboration of 13 European countries (...)” (<http://www.eli-np.ro/about-eli.php>).

We are presenting few characteristics of the ELI-NP relevant for the proposal: 1) ELI-NP is the largest research infrastructure project in Romania and requires considerable financial effort. Consequently, the expectation from the point of view of generating scientific results with social impact is very high. 2) The types of radiation beams that are available from the laser and gamma sources at ELI-NP can be used to produce effective technologies in bio-medical applications (diagnosis and treatment). 3) The uniqueness of ELI-NP sources creates specific opportunities that can be exploited to produce major scientific advances in bio-medical applications, particularly in imaging and radiotherapy. **The main question of this applications is:** How IFIN HH & ELI-NP may capitalize in the business on the scientific tradition, scientific results, brilliant scientific future based on the most powerful laser in the world, on the relation with the medical community to generate a Nuclear Medical Center (NucMed Center)?

## Potential stakeholders

Participation is open to all potential stakeholders: central and local public authorities, higher education institutions, the private sector, developers, investment funds and financial institutions. The main stakeholders are: a) Research: *IFIN HH – ELI-NP*; b) Regulatory bodies: *National Authority of Quality Management in Health* is in charge with setting up standards, the level of performance achievable and measurable, agreed upon by professionals, which can be consulted by the population to whom it is addressed. Also, evaluation performed by National Authority of Quality Management in Health surveyors, resulting in a classification of hospitals based on categories of accreditation (<https://anmcs.gov.ro/web/en/home-2-2/>); The National Authority will, also, the main partner in this project; *The National Commission for Nuclear Activities Control (CNCAN)* is responsible for the regulation, licensing and control of nuclear activities, including nuclear medicine (<http://www.cncan.ro/main-page/>); *The National Agency for Medicines and Medical Devices (NAMMD)* is a public institution subordinated to the Ministry of Health and it is the national regulator body in this field (<https://www.anm.ro/en/>); c) Universities: *Carol Davila University of Medicine and Pharmacy – Bucharest* (<https://umfcd.ro/despre-umfcd/>), *Iuliu Hațieganu University of Medicine and Pharmacy – Cluj-Napoca* (<http://www.umfcluj.ro/en/>), *Victor Babeș University of Medicine and Pharmacy, Timișoara* (<http://www.umft.eu/>), *Grigore T. Popa University of Medicine and Pharmacy – Iasi* (<http://www.umfiasi.ro/Pages/Default.aspx>), *University of Medicine and Pharmacy, Sciences and Technology of Târgu Mureș* (<https://www.umftgm.ro/en/home.html>), *University of*

*Medicine and Pharmacy of Craiova* (<http://www.umfcv.ro/en/>) Oncology research institutes, hospitals with nuclear facilities.

*National Company “Unifarm” Inc.* was founded in 1935, bearing various names over time. With over 80 years of experience in the national and international pharmaceutical market, it is currently one of the leading pharmaceutical and Para-pharmaceutical distributors in Romania.

### **The current medical situation**

In Romania, in the year 2018, there are 83,461 new cases of cancer, with 50,902 Romanians losing their lives due to this disease.

**The most frequent cancer types.** Compared to the latest GLOBOCAN report in 2012, figures show that incidence rates, as well as cancer mortality, have raised in Romania. Thus, the incidence of the top 10 most common cancers increased by about six percent from 2012, while mortality increased by nearly five percent in some types.

**The black ranking:** The highest incidence in Romania continues to be lung cancer (13.6%), followed closely by colorectal cancer (13.3%) and breast cancer (11.5%). The following cancers, as incidence, are prostate cancer (7.2%), bladder cancer (4.7%), stomach cancer (4.4%), liver cancer (4.3%), cervical cancer (4.1%), pancreatic cancer (3.8%) and uterine cancer (3%). These are the most prevalent types of cancer in Romania and account for almost 70% of all cases. The total number of oncologists in Romania was 495 in 2016 and more than 850,000 cancer patients were registered in the national registry.

The Romanian Nuclear Medicine Network consisted in 27 Nuclear Medicine Departments (Bucharest, Cluj-Napoca, Iasi, Târgu-Mureş, Timişoara, Brasov, Galati, Craiova, Deva, Sibiu. The rest of the counties do not have MN Departments and have to send patients to the nearest centers. In Romania and in Central and Eastern Europe there is a lack of opportunities for proper nuclear medical treatment. Romania lost its tradition in the field and the patients have to go in Turkey or other countries for treatment. This situation increases the cost per person. The pressure on the national budgets has become higher.

### **What was already done?**

IFIN HH / ELI-NP were part of **The European Cluster of Advanced Laser Light Sources (EUCALL) Project.** “EUCALL is a network between leading large-scale user facilities for free-electron laser, synchrotron and optical laser radiation and their users. Under EUCALL, they worked together on their common methodologies and research opportunities, and develop tools to sustain this interaction in the future. EUCALL has received funding from the European Union’s Horizon 2020 research and innovation programme and involves 11 partners from nine countries as well as the networks Laserlab Europe and FELs of Europe during the project period 2015 to 2018.” (<https://www.eucall.eu/>) **At the beginning of September 2018, IFIN HH / ELI-NP organized in Magurele a Nuclear Medicine Conference.** The purpose of the conference was to present to the industry the nuclear medical offer of ELI-NP, ELI-ALPS, ELI-Bbl. And to identify the real needs of the medical community from advanced research. The participants were: associations of the doctors from Nuclear Medicine, top management of the Romanian medical universities, Managers of hospitals, Governmental agencies in Medical Field.

The main conclusions of the conference are the following:

**1. working group** – the participants decided to create a group of experts from IFIN HH / ELI-NP, Magurele High Tech Cluster (MHTC), National Authority for Quality Management in Health System, medical Romanian universities, and hospitals with nuclear medicine activity. This group will operate like a think tank for future developments, especially, to design the Nuclear Medicine Center and to encourage developments of joint research projects.

**2. Nuclear Medicine Center** – The proposal came out from IFIN HH / ELI-NP and the National Authority for Quality Management in Health System.

**3. Joint Research Projects between IFIN HH – ELI-NP and innovative companies** – The idea of such kind of cooperation was developed in the last few years and seems to be the most profitable for both sides: research and business. IFIN HH / ELI-NP and MHTC launched the concept: *Growing Together*.

**4. Training for doctors and physicists working in nuclear medicine hospitals** provided by the [Nuclear Training Centre](#) (CPSDN) – IFIN HH.

NucMed Center Project may have three main components: 1) Creating a NucMed Center – **we do not know how to do this**; 2) Developing financial instruments to finance a part of the operation in Magurele and in the rest of the country – **we have some ideas**; 3) Enhancing the INNOGATE 21 on-line communication platform (audio – video) created by IFIN HH – ELI-NP and Magurele High Tech Cluster to be a voice for the sustainability of the NucMed Center.

Here are the main questions suggested by the challenges we are seeing from now in the field on business development:

**A.1. the main question is:** How IFIN HH & ELI-NP & MHTC may capitalize in the business on the scientific tradition, scientific results, brilliant scientific future based on the most powerful laser in the world, on the relation with the medical community to generate a NucMed Center?

**A.2.** Which is the best approach for developing a 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 specialised in nuclear medicine, private entities from medical industry? **A.3.** What would be the most appropriate strategy to transfer IFIN HH – ELI-NP research results to the industry? **A.4.** In the first stage of drawing the business model, IFIN HH & ELI-NP's offers for the market should include only the main requested scientific results by the medical community, or is better to put on the table the whole potential package even the results are not there, yet? **A.5.** What would be the links between a start-up / spin-off and IFIN HH – ELI-NP?

**B.1.** What financial instruments could be developed for such kind of project? **B.2.** Who may be the partners and public institutions to be involved in? **B.3.** What risks are generated by the financial instruments for the economic stability of research institute and for SMSs? **B.4.** There are institutions in the market to give guaranties for such financial instruments initiated by the major research infrastructures?

**C.1.** How to protect scientific data and the data of the patients? **C.2.** How to develop internal communication flow of information to convince the researchers that the relation with the industry has utility for their activity and it is not a lost time?