Oncidium foundation

Access • Education • Hope

FEBRUARY 2ND, 2023

Radiotheranostics Today

Voicing the Challenges and Opportunities of Radiotheranostics for Cancer Care

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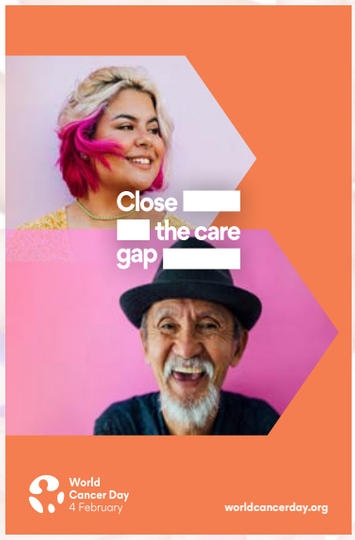
February 4th is World Cancer Day!

Access for all in the fight against cancer

A day celebrated to raise awareness of cancer and encourage equal access to cancer care for all. World Cancer Day is a global initiative and call to action to end cancer care inequity.



But how does the foundation take action at it's own level? An integral part of our mission is to raise awareness, bride gaps and enhance access - regardless of origin or financial situation - to a potential life-saving option for people living with cancer.

We stand with our colleagues in advocating for a more equitable healthcare landscape for patients. Together, we can create a better world for our cancer patients and close the care gap!

From challenges to opportunities, from awareness to readiness, discover what the voices of Oncidium have to say about bringing forward Radiotheranostics Today.

Ready to talk radiotheranostics with Oncidium foundation?

- Zoom on the radiotheranostics situation in your country
- Evolution, projects and challenges in your region
- Focus on a particular application
- Patient/practitioner interview etc.

Contact us to contribute to the next issue!

Focus on the NOBLE Registry in Egypt: Challenges, Aspirations and Future Perspectives for People Living With Prostate Cancer

By Dr. Omar Yehia and Dr. Cristiana Gonçalves Gameiro

Dr. Omar Yehia, Director of the Theranostics Unit at the Misr Radiology Center and Principal Investigator in Egypt for the NOBLE Registry joins Dr. Cristiana Gameiro, Scientific Advisor at the Oncidium foundation in a discussion regarding the NOBLE Registry, an international clinical collaboration for the development of ^{99m}Tc-iPSMA SPECT imaging for prostate cancer. The aim of the talk will be to focus on the NOBLE Registry within the Misr Radiology Center, to discuss the challenges, aspirations and future perspectives for the Registry and for people living with prostate cancer. ^{99m}Tc-iPSMA SPECT is authorized for investigational use only.

Dr. Omar, could you please start by explaining the challenges that you faced when recruiting patients for the NOBLE Registry?

The main challenge is probably recruiting patients who are a little bit afraid to join something new. They do not know what is going on and I think this is the toughest part and it requires good communication skills between the physician and the patient. The physician has to explain what he is going to do and the value that the patient is expected to have.

Clear communication between the physician and the patient is essential for this part because many patients could have the opportunity to receive potentially good investigational drug and effective treatments before they are being licensed/approved. And that is the only way they can receive a potentially better drug. We, the whole community, must raise awareness about this. So again, the most important thing is to raise awareness and educate the general public about the benefits that they could have after joining these clinical trials.

> *The most important thing is to raise awareness and educate the general public about the benefits that they could have after joining these clinical trials.*

Are there any other challenges such as image reading, costs, training or logistics?

At first, we faced a problem with the radiolabelling procedure, but as we have many sites around the world, we were able to have general routine meetings and we could solve it quickly, all of us reunited around the same table.

So, these challenges were more easily solved thanks to a strong community participation in NOBLE and their collective efforts?

Yes it was. Everybody helped each other which makes me think that we are building a strong community. It is a good thing that we are all friends now that we have connected with many doctors around the world. We all share the same passion for nuclear medicine and the awareness it necessitates. This is also why some of us joined the Oncidium foundation, which raises awareness on nuclear medicine. Therefore, we are all able to connect easily and talk about the problems we sometimes have to face and find solutions together.

> *We are all able to connect easily and talk about the problems we sometimes have to face and find solutions, together.*

Your message here would be that it is very important to have strong connections and to share experiences so that everything is smoother for all sites. Especially for sites where they lack experience…

Indeed. And that is very enriching because our backgrounds are completely different as we are not all talking the same language and as we do not share the same culture.

I believe that raising awareness, especially on radiotheranostics is very important, since it is a new discipline when compared to conventional drugs. Therefore, I think the role of foundations, such as the Oncidium foundation is essential to educate the community in general: patients, drug providers, hospitals and nurses, etc., I hope it is going to be a little bit more positive in terms of future perspectives. What do you expect from NOBLE in your institution?

To be continued page 03

I long for a bright future regarding the NOBLE Registry. I sincerely hope that one day, we will be able to select patients for lutetium therapy based on Technetium-^{99m}Tc-iPSMA SPECT as we have wider access to Technetium generators and therefore, could be able to perform Technetium scans on a regular basis in many countries.

I strive for better access all around the world, in rural areas for instance, because the doses are already available, which means that no big infrastructures are needed, only the therapy. Doses could be delivered based on the selection criteria that we are planning to evaluate with ^{99m}Tc-iPSMA SPECT. Ultimately and depending on the results, we will be able to have access to a scan that could not only image the bones but also lymph nodes and all metastases.

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When do you think this will be more routine in your center? Do you think it will be possible within two or three years, for example?

For men, in the future, we should stop doing bone scans for prostate cancer. I think we should either use Technetium-99m iPSMA with CT instead of doing a bone Scan and CT or do a PSMA PET-CT. I think that it will be the case within the five coming years.

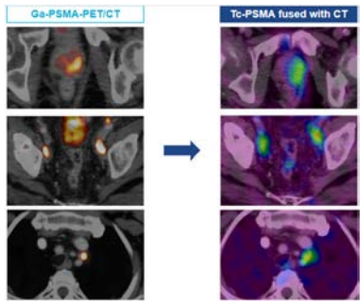
In Egypt, this will probably take two to three years if the kit is available and if the prices are not too high. This would probably encourage people to use Technetium-99m iPSMA instead of resorting to bone scans and change their mindsets.

So, based on your experience, do you have any other advice to advance the use of ^{99m}Tc-iPSMA?

As far as Egypt is concerned, the efforts should be concentrated price wise and also the guidelines are very important, more particularly when it is possible to have reimbursement because the insurance companies are going to pay.

As for countries where there is no real reimbursement, and where the patient pays out of his own pocket, the most important things are knowledge, data and the guarantee of the benefits for the patient.

The only positive point about the fact that it is sometimes impossible for the patient to be refunded is that things tend to go faster, since he is going to pay anyway.



Thank you very much for answering my questions. I'm very excited about what I have heard in terms of perspectives for the selection of patients who can access therapy, and about the fact that you will find solutions to give them more options for treatment. These patients sometimes do not have any more options because nothing works and then we discover that radioligand therapy may be able to help them.

If I can add one more thing: I truly believe in radioligand therapy, specifically with Lutetium-based products targeting PSMA. I have witnessed marvelous responses: patients that were coming in wheelchairs, who could not move nor go to the bathroom are now traveling and back to work again. This is why I want to focus more and more on the NOBLE registry and reach this endpoint. The aim is to allow more patients to have access to therapy because it is truly life changing. This is the end goal for all of us.

Thank you very much. It is very nice to conclude with a very positive note and wish you a very bright future indeed!

Yes, I hope so. Thank you very much. It was my pleasure.

Learn more about The NOBLE Registry.

Dr. Omar Yehia Hussein
- Principal Investigator NOBLE Registry (Misr Radiology Center)
- Advisory Board Member and Ambassador at the Oncidium foundation

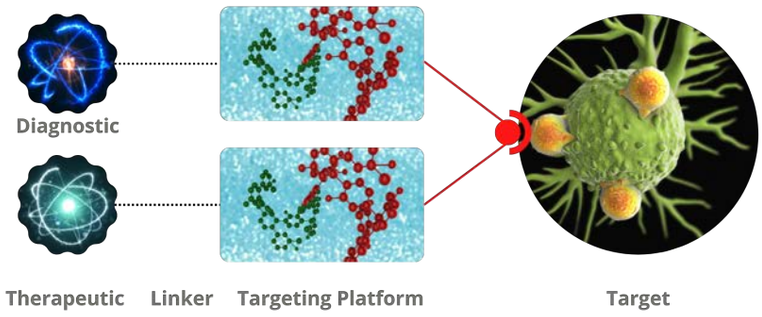
Cristiana Goncalves Gameiro Ph.D.
- Product Manager at IBA Radiopharma Solutions
- IBA Honorary Fellow
- Scientific Advisor at the Oncidium foundation

Radiopharmaceutical Supply Chain

By Leila Safavi

With the success of Lutathera®, the promising potential of targeted alpha therapies, and the growth of radiotheranostics, the demand for radioisotopes aimed at drug development and clinical use will only increase in the coming years. Addressing concerns of access and availability of radiopharmaceuticals is high priority for ensuring patients can benefit from these lifesaving diagnostic and therapeutic procedures.

Radiopharmaceuticals, whether used for diagnostics, therapy, or as a theranostic, at an elementary level, are composed of three components:
1) the pharmaceutical, which acts as a vehicle taking the drug to the intended location to be treated or diagnosed,
2) the radioisotope, which emits radiation used by the imaging device for diagnostics, or the emitted radiation kills the cancer cells and eventually kills the tumor for therapeutic applications,
3) a linker that connects the pharmaceutical and the radioisotope.



Radioisotopes, the key active ingredient of radiopharmaceuticals, have short half-lives (the amount of time required for one half of the quantity of radioisotopes to decay) requiring a supply chain without any setbacks or delays. Development of each component of the radiopharmaceutical, combining them into a final product, and administration of the drug to the patient contributes to a multifaceted, complex and time-constrained supply chain.
Due to the decaying nature of radioisotopes, it's a fight against time from the moment it is produced until the product reaches the patient. Therefore, the production and administration of radiopharmaceuticals require flawless planning and foresight. Additionally, since these pharmaceuticals involve radioactive material, additional layers of safety and regulations are required.

The supply chain starts with target development and target fabrication. These targets are irradiated either by nuclear reactors or particle accelerators to produce radioisotopes. As soon as the radioisotope is made, it starts to decay and cannot be stored or stockpiled. Any delays and disruptions post-production of the radioisotope can ultimately result in a patient not receiving the planned treatment or diagnosis.
Post irradiation, the targets are removed from the reactor/accelerator, cooled, and transported to a processing facility to process the target, separate the radioisotope, and obtain it in a form that can be compounded into a pharmaceutical. In cases where the radioisotope is a by-product of nuclear waste or a decay product of a long-lived isotope and no irradiation is required, the targets go straight to processing to separate the radioisotope and develop it into a form that can be compounded into a radiopharmaceutical. Post-target processing, the radioisotope is transported to radiopharmaceutical manufacturers, where it is compounded into a drug or a generator, depending on the radioisotope and application. Then, the radiopharmaceutical or generator is distributed to pharmacies, hospitals, and healthcare centers and, from there, ultimately reaches the patient for either diagnostic, treatment, or a combination of the two.

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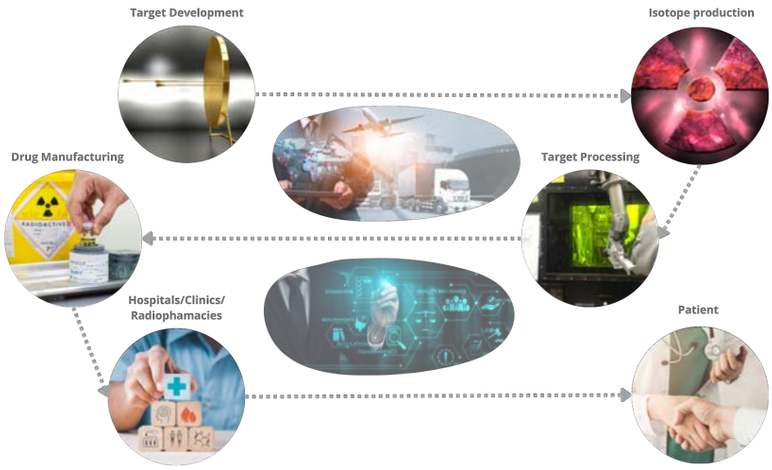
Radiopharmaceutical Supply Chain.

After passing the first step of target development, you are dealing with radioactive material, which adds layers of complexity, additional safety, and regulations to every aspect of the supply chain. The entire supply chain is intimately intertwined with logistics, transportation, and strict regulations. Therefore, ensuring it runs flawlessly with the highest safety standards requires immaculate planning and highly skilled experts. With radioactivity being harmful for personnel exposed to excessive doses, there are also increasingly stringent safety requirements and



Each step of the supply chain requires dedicated facilities (nuclear reactors, processing facilities, manufacturing facilities, hospitals, pharmacies, etc.), flawless transportation and logistics between facilities, and highly skilled experts (nuclear reactor operators, scientists, engineers, regulatory experts, physicians, radiation safety, health physicists, business and administration experts, etc.).

Over the past two decades, we have witnessed disruptions in the radioisotope supply chain, particularly concerning Molybdenum-99/Technetium-99m production. These disruptions indicate that the radioisotope supply chain is vulnerable, and we must manage it proactively; otherwise, overcoming production/supply challenges can take many years. Therefore, it is essential that early in the development process, radiopharmaceutical manufacturers secure a reliable radioisotope supply source to meet their needs from the initial R&D stage to commercial scalability and, ultimately, clinical use.

If you have experienced challenges with the radiopharmaceutical supply chain, we would love to hear from you.

Leila Safavi, PhD.
Oncidium foundation
Ambassador
Irvine, USA

Have you met our fantastic team of Ambassadors in the US?

Focus on Lutetium-177

By Dr. Richard Zimmermann

Lutetium-177 (^{177}Lu) flies high since it became available at large scale. In fact, all radionuclides that have demonstrated a potential of easy and cheap industrialization do have a future.

Lutetium-177: a convincing champion

This situation happened during the early 2000's, at a time when radiotherapeutics were mainly labeled with Iodine-131 (^{131}I) and Yttrium-90 (^{90}Y). These two radionuclides had flaws and researchers were looking for alternatives, but were limited by willingness to industrialize production. Iodine is a labile atom, to be bound only covalently to molecules while ^{90}Y is a pure beta emitter not allowing imaging and with quite a high energy. With its half-life of 6.73 days, a beta emission of 498 keV (78.6%) and 177 keV (12.2%), also with a small but sufficient gamma emission of 208 and 113 keV, ^{177}Lu looks like an ideal isotope for therapy. The labeling chemistry allows also binding with both ^{68}Ga and ^{225}Ac without changing the structure of the molecule, permitting the development of radiotheranostic families in a sequence PET imaging tracer with ^{68}Ga, beta-therapy (^{177}Lu) and alpha-therapy (^{225}Ac).

At that time, Holmium-166 (^{166}Ho, half-life 26.8 hours, gamma at 81 keV, beta at 1,855 and 1,774 keV) showed in terms of half-life and energy a profile somehow between the ones of ^{177}Lu and ^{90}Y. If the attention would have been more focused on the production of ^{166}Ho, the worldwide developed radiotherapeutics would probably today be based on this radionuclide instead. If a radionuclide finds a champion that promotes and develops it at the right time, then there are great chances that this radionuclide reaches the top of the list. ^{166}Ho did not find this champion and will probably remain in a drawer for a long time, as too close to ^{177}Lu.

Opportunities and challenges

The first production route of ^{177}Lu was based on direct neutron irradiation of ^{176}Lu in a reactor. It provides a carrier added (ca) quality of ^{177}Lu, i.e., a mixture of cold ^{176}Lu and radioactive ^{177}Lu, which contains about 20% of active isotope, end of extraction. One has also to take in account that ^{177}Lu decays back in ^{176}Lu and the waiting time between end of irradiation and injection to patient increases the amount of ^{176}Lu and decreases considerably the ratio ^{177}Lu/^{176}Lu. When using this mixture for vector labeling, one must take into account that the labeled drug is mixed with 80% of the non-active (cold) Lu-analogue. This is not an issue if this cold by-product does not generate a toxic side-effect. All molecules developed on this basis so far, including the marketed ^{177}Lu-Oxodotreotide (^{177}Lu-Lutathera) have proven both efficacy and absence of interference of the cold labeled molecule. This becomes slightly more complicated when it comes to label vectors with very high molecular masses, such as antibodies, which are also very expensive to produce. In this case, pure ^{177}Lu, i.e., referred to as non-carrier added (nca) radionuclide would show a great advantage, either in terms of reducing the part of the wasted vector costs, or in avoiding interference between the larger amounts of cold product compared to the active one.

Unfortunately, the direct route generates another unwanted by-product, namely ^{177m}Lu. During the irradiation process which lasts between one and two weeks, the produced ^{177}Lu is also submitted to the neutron bombardment and transforms itself in ^{177m}Lu, another Lutetium isotope with half-life of 160 days. The ca ^{177}Lu not only contains a very large excess of ^{176}Lu, but also some increasing amounts of ^{177m}Lu. It has been demonstrated that this amount of radioactive ^{177m}Lu does not introduce a safety risk at the level of the patient. In fact, using ca ^{177}Lu or nca ^{177}Lu does not make any difference at the level of the patients in terms of efficacy or side-effects. ca ^{177}Lu has also the advantage to be less expensive to produce. The first ^{177}Lu-labelled drug that reached the market, namely ^{177}Lu-Oxodotreotide (Lutathera®) is based on ca ^{177}Lu.

The real problem with ^{177m}Lu is its long half-life, as a large part is eliminated from the patient through the urinary track and is then collected in the hospital waste tanks. These waste tanks can be emptied when the level of total radioactivity goes below a predefined radioactivity threshold and the best way to reach that level, is simply to wait for almost full decay. When it comes to radionuclides with half-lives of a few days to a week, the problem can be solved within a quarter, but when it comes to a half-life of 160 days, even at lower amounts, it creates a true issue for hospitals. Depending on the size of these waste tanks, it has been calculated that in some cases, the maximum number of patients to be treated per hospital could be limited to 2 per week. Alternatives have been proposed, like having patients using diapers or having patients treated ambulatory. Diapers need also to be stored in containers as waste for several years while ambulatory treatment will simply increase the radioactivity level in rivers.

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An alternative solution

Very quickly the alternative solution of producing ^{177}Lu via an indirect route was put in place. Irradiation Ytterbium-176 in a reactor leads to ^{177}Yb which decays in ^{177}Lu. Lutetium can easily be separated from Ytterbium leading to pure ^{177}Lu, containing neither excess of ^{176}Lu nor ^{177m}Lu. Nowadays, this way to produce the nca ^{177}Lu is the preferred one and Lutathera® will probably remain the only drug on the market labeled with ca ^{177}Lu. Nowadays, both Novartis and Point Biopharma are working on the development of the analogue of Lutathera®, based on nca ^{177}Lu. The recently approved ^{177}Lu-Vipivotide tetraxetan (Pluvicto®, prostate cancer) is based on nca ^{177}Lu.

At a certain point, the concern about access to ^{176}Yb was raised, as this starting material had a unique source in Russia. In the meantime, the price of this material was multiplied by a factor five. Some North American and European companies are now investing in new tools and new technologies to produce ^{176}Yb, and it is to expect that this Russian monopoly situation will be definitely broken by 2024-2025. This does not tell that the price of ^{176}Yb will decrease, but at least, there will be no issue anymore for access to this important raw material.

A rising star to answer a growing number of patients

More than fifty ^{177}Lu-labelled molecules having entered clinical development or being close to reach that stage, have been identified. Among them, four molecules have a chance to reach the market within the next 4 years. The first molecules target of course prostate cancer and neuroendocrine tumors, but the following generation is exploring kidney cancers, non-Hodgkin lymphoma or more generally new biological mechanisms such as FAPi, CCK2R, NTR-1, CXCR4, etc… in different solid cancers.

Everything seems to be on track for the future of nca ^{177}Lu. Unfortunately, at this stage, we must consider a new issue. If one looks closely at the presently needs in terms of doses, the industry can cope with the few ten thousand patients that are treated yearly. However, when entering the field of prostate cancer which claims a worldwide prevalence of 12 million patients, if only 1% of these patients could benefit from the therapy, we will enter in an era needing about half a million doses per year. This amount concerns one single indication. Other large indications such as breast, lung or colon cancers are also the targets of the main investors and if one cumulates the target patient population for all these indications (and not molecules), we could realistically reach by 2030-2032 more than one million of patients to be treated associated to the need for several million doses per year. Translated in production capacity, this exceeds by several factors the capacity of production of all the reactors at a worldwide level. Even if one includes the Pallas reactor that was recently approved for building in the Netherlands, but is supposed to replace the HFR, and the new South Korean and French reactors that should then be operational, it is estimated that capacity of production will, by that time, be sufficient to treat only about 500K patients a year. Building a new reactor is out of scope within this time frame and budget.

So, there are three alternatives to be considered:
a) substituting reactor production of non-profitable radionuclides, such as ^{99}Mo, by ^{177}Lu,
b) invest strongly and quickly in non-reactor-based production solutions, which is possible, or,
c) for companies with drugs still at the preclinical stage, to already consider switching to another radionuclide that has better chances to become industrially available by 2030, such as ^{67}Cu, ^{117m}Sn, ^{131}I or… (already taking in account that ^{161}Tb will be in a same situation as ^{177}Lu).

… But this is another story.

Richard Zimmermann Ph.D.
President & Founder at Oncidium foundation

Introducing you to our new project: "Theranostics Insights"

To highlight radiotheranostics for cancer care, discover our brand-new educational material to get more "Theranostics Insights". Every month, we focus on a different molecule, thus expanding knowledge about all you need to know on radiopharmaceuticals.

Join us on *LinkedIn.*
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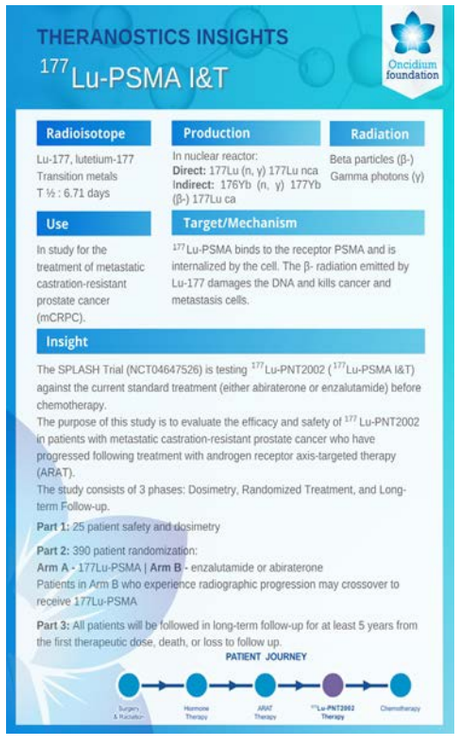

Nuclear Medicine in Brazil: History, Current Status and Next Objectives

By Dr. Alice Viana and Dr. Adelina Sanches

The start

Brazilian nuclear medicine history starts after the second war finished. About one year later, in 1946, Brazil was one of the countries involved in the United Nations Atomic Energy Commission foundation; and in 1953, right after the "Atoms for Peace" speech, by Dwight Eisenhower, and that received support from the United States of America to build the first Brazilian research nuclear reactor.

The reactor was built in the area of the current University of São Paulo (USP), today considered one of the best universities in Latin America. Not by coincidence, today, in the exact same place, we can find the Instituto de Pesquisas Energéticas e Nucleares (IPEN), created in 1956, and responsible for the first productions of radiopharmaceuticals in the country.

IPEN was born as a unit of the (also founded in same year) Comissão Nacional de Energia Nuclear (CNEN), with the aim of recommending and controlling necessary measures for the political orientation of atomic energy in all its aspects. Responsible for the national production of ^{131}I in the late 50's, IPEN nationalized more and more radiopharmaceuticals. In the 80's, they started to manufacture ^{99}Mo/^{99m}Tc Generators and cold kits, as well ^{18}F-FDG, ^{153}Sm, ^{201}Tl in the 90's and, in 2007, started the labeling and commercialization of ^{177}Lu-DOTATATE.

Regulatory status

In 1988, the new Brazilian constitution established a State monopoly for radiopharmaceuticals (and non-medical radioactive products) under the responsibility, regulation and supervision of CNEN. Later, in 2006, with the high demand for FDG in the country, a Constitutional amendment (nº 49/2006) was approved, that allowed private companies "the production, marketing and use of radioisotopes with a half-life of two hours or less". The amendment also opened the market for the manufacture of cold-kits by private companies. Since a half-life limitation was imposed, the production of ^{99}Mo/^{99m}Tc generators were still under the government monopoly. But in 2022, due to the pressure of society, private companies and other players, another Constitutional amendment was approved (118/2022). This one allowed the manufacture, by private initiative, of all types of radioisotopes for medical use.

With the end of the monopoly came the need for regulation of health and sanitary aspects of the products by the Brazilian health authority (ANVISA – Agência Nacional de Vigilância Sanitaria). The agency listed 44 products with market authorization. Currently ANVISA is part of the Pharmaceutical Inspection Co-operation Scheme (PIC/S), and the legislation that establishes the rules for registration, notification, import and quality control of radiopharmaceuticals is the RDC 451/2020, that is aligned with USA and Europe's radiopharmaceutical legislations. Another important recent regulatory modification was the creation of the National Nuclear Safety Authority (ANSN - Autoridade Nacional de Segurança Nuclear) that is now responsible for the nuclear energy sector regulation, while CNEN and its institutes will remain responsible for the manufacture and research (Law nº 14.222/2021)

Nuclear medicine in numbers

Cyclotrons: 10

Radiopharmacies: 3

Nuclear medicine services: 474

SPECT equipments (approximate number): 600

PET equipments (approximate number): 150

Challenges and opportunities

Although the main cold-kits and radioisotopes are available in the country, due to its continental dimensions and the years of public monopoly, the access to radiopharmaceuticals is not evenly distributed across the country. If we compare, for example, our airline network with the United States, the Brazilian one is about 10 times smaller and only 2 airline companies transport radioactive material. This is critical for ^{18}F products, Brazil has 10 cyclotrons in commercial operation, most of them concentrated in the Southeast and South regions, none in the North region. These are also the regions that concentrate more than 60% of all nuclear physicians and equipments for PET and SPECT.

These fragilities need to be addressed, the country needs a coordinated development plan for the nuclear medical field, with more investment and incentives for the establishment of nuclear medicine services in under-served regions. Besides that, with the large intellectual capital the country has, developing new radiopharmaceuticals for the national and international markets and reaching independence in the area of research and development are other points to be achieved.

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Radiotherapeutics available in Brazil

^{90}Y microspheres (Sirtex): liver cancer

^{131}I (IPEN) = thyroid cancer

MIBG-131 (IPEN) = pheochromocytoma and neuroblastoma

^{153}Sm (IPEN) = bone cancer

^{177}Lu-DOTATATE (IPEN) = neuroendocrine cancer

^{177}Lu-PSMA (Grupo RPH) = prostate cancer

^{223}RaCl (Xofigo – Bayer) = bone metastasis due to prostate cancer

The project of the Brazilian multipurpose reactor (RMB) is a great step in this direction. The RMB will be able to produce the radioisotopes that are currently imported, reducing the risk of shortages and lowering the costs of radiopharmaceuticals. The RMB construction, together with a more clearly regulated sector and the definitive end of public monopoly may attract more national and international players for the nuclear medicine sector in Brazil, and ultimately increase the access of Brazilians to the benefits of nuclear medicine.

Alice Viana, PhD.
Foundation Development Manager

Dr. Adelina Sanches
Oncidium foundation Ambassador
Salvador, Brazil

Brazilian perspectives

In The future of nuclear medicine globally looks promising as new technologies, radiotracers and techniques are being developed, tough, for the next five years Brazilian nuclear medicine community will face great challenges, like keeping the use of nuclear medicine sustainable, with great needs in improving infrastructure and logistic supply chains, also economic viable, and it will rely on investment in education, technology, changes in government policies, and the overall state of the healthcare system in the country. Only than we can expect to fulfill our potential and continue to grow and play an important role in the diagnosis and treatment of various medical conditions for all Brazilian population. We believe in planting seeds for this future, strengthen partnerships like the ones we have with CNEN/IPEN and Oncidium, making new ones and bringing good quality education to our nuclear medicine community.

Dr. Rafael Lopes,
President of the Brazilian Society of Nuclear Medicine (SBMN)

In 2019 I became an Ambassador of the Oncidium foundation in Brazil. Because of the pandemic, we could not play our role fully. This year, with the resume of face-to-face activities, the Oncidium foundation in Brazil formed a partnership with the Brazilian Society of Nuclear Medicine (SBMN) and has increasingly provided information to patients and health professionals about theranostics. What I hope for the coming years is that we will be able to reach more and more people, making theranostics widely known and accessible. *Dr. Guilherme Rossi,*
Ambassador Oncidium foundation

Focus on RLT Actors: SPARC-Europe: a Gateway for RLT in European Policy

The Stakeholder Political Alliance for Radioligand Cancer Therapies (SPARC-Europe) is a **policy initiative** aimed at building an adequate policy environment for radioligand therapies (RLTs) and ensuring that EU policy initiatives reflect the specific characteristics of this innovative type of treatment.

Although radioligand therapies are well-known among nuclear medicine and oncology experts for their far-reaching benefits, they are a largely unexplored topic at the policy level and, as such, have not been addressed concretely by European policies. With the European health policy landscape constantly growing and Europe's Beating Cancer Plan initiatives being now implemented across the EU, the next years will be paramount in addressing RLTs barriers and in ensuring an effective environment is in place to foster innovation and support cancer patients access to treatment.

Important new paradigms in cancer care must be therefore addressed to ensure that the EU can build a sustainable plan that incorporates changing science and shaping patients' outlooks. RLTs present a treatment paradigm shift in this sense, and a platform is required to provide European policymakers with adequate input and expertise and build momentum for redefining policies in cancer care.

SPARC-Europe is one of those platforms welcoming this needed change in perspective, thanks to the Alliance's experts working in the field of nuclear medicine, internal medicine, oncology, and patient advocacy.

Where we stand today

Composed of a Steering Committee, politically patroned by Members of the European Parliament, and supported by funding partners, the Alliance has continuously been working towards its objectives, including bridging inequalities in hospital infrastructure at European and regional levels for accommodating RLT and raising awareness among patients.

In fact, the Alliance has thoroughly engaged with policymakers through public consultations, bilateral meetings and organisation of policy events. Its experts also developed important materials which to date improved stakeholder understanding of radioligand therapies, such as the High-Level Position Paper on Improving Access to Radioligand Cancer Therapies in the context of Europe's Beating Cancer Plan; the Investment Pathway Guide, which encourages national and regional stakeholders to benefit from EU funding mechanisms and address RLT-related challenges.

This piece of work was accompanied by the release of a patient testimony video, where three patients from Belgium, Ireland and Spain share their experience with RLTs and their recommendations to policymakers on how to improve the treatment and its accessibility in the future.

Despite the numerous efforts undertaken, there are still several steps to take and many obstacles to overcome at the European level and beyond, so do make sure to keep an eye on the Alliance's future work by visiting the official website. For any questions that you may have to better understand SPARC-Europe's engagement in the policy sphere, the Policy Secretariat will be delighted to address any queries via its email address: secretariat@sparc-europe.com

SPARC-Europe membership
Members of the European Parliament: Brando Benifei (S&D, IT), Marian-Jean Marinescu (EPP, RO)

Steering Committee Members: Mark McDonell (INCA), Martyn Caplin (Royal Free Hospital), André Deschamps (Europa Uomo), Ignasi Carrió (Autonomous University of Barcelona, Research Institute, Hospital Sant Pau), Nicola Fazio (European Institute of Oncology), Ken Herrmann (University Hospital Essen), Luka Ležaic (University of Ljubljana), Dermot O'Toole (Trinity College Dublin), Bertrand Tombal (Université Catholique de Louvain, Cliniques Universitaires Saint-Luc).
Observers of the Alliance: Josep Maria Borrás (Catalonia Cancer Strategy)
Secretariat of the Alliance: RPP (Kinga Wójtowicz, Emily Philips, Carmen Salvador Arnau)
Funding partners: Advanced Accelerator Applications, Isotopen Technologien München (ITM)
Provide input in policy debates on the needs of healthcare systems to welcome innovative cancer therapies.
Demonstrate the expertise and provide expert knowledge to support decision-and policymakers in strengthening European cancer care, ensuring a unified guidance for accommodating radioligand therapies throughout Europe.

Focus on RLT Actors: Health Policy Partnership Updates

The UK Molecular Radiotherapy Consortium

We are pleased to announce the inauguration of the UK Molecular Radiotherapy Consortium!

Across the UK, there is not currently equitable access to molecular radiotherapy (MRT) services. This has been reinforced in several documents, including: Molecular Radiotherapy in the UK: Current Status and Recommendations for Further Investigation – Report 23, Review of molecular radiotherapy services in the UK, National Cancer Research Institute (NCRI) Clinical and Translational Radiotherapy Research Working Group (CTRad) Priorities 2022–2025, British Nuclear Medicine Society (BNMS) position statement on molecular radiotherapy, Health system readiness for radioligand therapy in the UK and a proposal to set up radiotherapy networks in England.

These documents highlight the need for a cohesive voice to push for change to ensure MRT is promptly and readily available to people who may benefit from it. Prompted by these documents, Dr Darren Leaning initiated discussions around a UK MRT Consortium in the hope of bringing together national experts from different professional organizations and patient advocacy groups across the UK.

The UK MRT Consortium is an alliance of clinicians and patient advocates formed to bring about change. The overarching aim of the Consortium is:

> "To support equitable patient access to and safe delivery of evidence-based theranostic MRT and provide a multidisciplinary forum for all relevant stakeholders engaged in MRT to advance research, knowledge and policy engagement on MRT across the UK."

To date, the Consortium has held two meetings, and many members have come together to send a letter to the UK Secretary of State For Health, calling for an urgent review of MRT services.

The inauguration of the UK MRT Consortium marks a milestone for nuclear medicine provision in the UK. We hope that its establishment will serve as a promise to people with cancer, healthcare professionals and governing bodies that a comprehensive MRT service can be established in the UK.

The Health Policy Partnership

[research, people, action]

HPP call for information: RLT initiatives

Do you know how people are getting ready for the future of radioligand therapy? If so, The Health Policy Partnership (HPP) wants to hear from you! With your input, HPP aim to uncover new learnings and build a public resource to help others plan and deliver radioligand therapy to the people who could benefit.

There are a number of barriers to integrating radioligand therapy into care. With many new radioligand therapies on the horizon, now is the right time to be sharing learning of innovative ways to ensure health system readiness for radioligand therapy.

HPP are looking for examples of successful activities to include in the upcoming Radioligand Therapy Readiness Hub. The Readiness Hub will aim to expand sharing of knowledge and learnings between different locations, care settings and cancer types.

Have you been part of an activity that has addressed barriers to appropriate use of radioligand therapy? Have you planned for how you will bring radioligand therapy into clinical care? Have you helped develop materials to support people who would benefit from radioligand therapy? If so, please share your experiences with us. To participate, visit:

https://www.surveymonkey.co.uk/r/G8MMD2G

What's up Oncidium foundation?
Reflecting on 2022 achievements

It is this time of the year to look back and reflect on our achievements and what a year it has been! We endeavored daily to ensure continuity in our mission and this was achievable thanks to our continuously growing community, namely through our fantastic Ambassadors and Friends of Oncidium.

Oncidium foundation Ambassadors

This year has been marked again by the motivation of our well-established and recently joining Ambassadors. With 44 dedicated radiotheranostics enthusiasts, present in 22 countries, we were able to reach our objective to bring forward the technology. Looking forward to continue this collective effort in 2023! Get involved.

2022 highlights

PATIENT SESSION
THERANOSTICS
WORLD CONGRESS

TESTIMONIAL
FERNANDO ACOSTA
LU-177 RLT

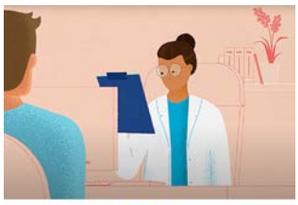
AMBASSADORS
MEETING
EANM 2022

What are radiotheranostics for cancer care?

Dealing with a cancer diagnosis can often be overwhelming, especially when discovering a technique that is still unknown to many. Still wondering what radiotheranostics are? Are you in contact with patients and wish to demonstrate how radiotheranostics work? Learn more and find some answers to your most frequently questions regarding radiotheranostics for cancer care.

Watch our new illustrated videos.

WHAT ARE
RADIOTHERANOSTICS
FOR CANCER CARE?

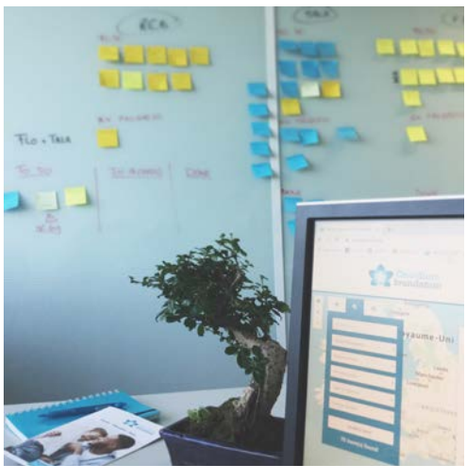


DOCTOR, WILL
RADIOTHERANOSTICS
MAKE ME RADIOACTIVE?

What's up Oncidium foundation?

Entering 2023: continuity, growing community, enhanced accessibility and more opportunity

Entering 2023 with a lot of things to do to tackle challenges and create new opportunities. The Oncidium foundation team continues to endeavor to increase awareness and access to radiotheranostics options for cancer care. Bridging gaps and building hope can only be achieved through continuous exchanges and collaborations on projects that can help enhance visibility and spread the word, to as many people as possible, globally. So, what's next in line?



What's in the pipeline?

Now that the foundation is up & running, the team is currently busy implementing 5 long-term vision projects to:

- Enhance patients access
- Accelerate clinical developments
- Improve production capacities
- Support early-stage developments
- Increase partnerships

Stay tuned!

New opportunities, growing team!

With new ambitious projects comes greater responsibility. Have you checked your inbox lately? If yes, then you might have come across our two new colleagues: welcome to the team, Alice and Sybille!

Alice Viana, PhD.
Foundation Development Manager

Sybille Vermeylen
Executive Assistant

Coming soon: Tackle Cancer Challenge - 2nd virtual race

Radiotheranostics on the move with the Oncidium foundation

Last year's goal was to initially reach 5000km in 15 days.

- Achieved: 15373 km
- Runners: 300
- Countries: 12

So can we do better this year?

Join our global race that aims to encourage participants to move together and get actively involved to raise awareness about the benefits of radiotheranostics in cancer care. After downloading the application and paying for the registration ticket, participants can start the challenge, do sports and make a difference !

Contact us to participate and get exclusive information about the event.
Learn more on how to become a sponsor.

Supporters of the Oncidium foundation

Support the foundation and join the fight against cancer

Supporting the foundation will allow to finance research and development of new radiotheranostics, but also to reach directly patients thanks to contributions that will help finance treatments using radiotherapeutics technology.

We know that this path is not easy. We know the importance of finding the right and nearest doctor, understanding the diagnosis and evaluating treatment options. Thus, it is our mission to educate, raise awareness, and support people living with cancer and their loved ones in this daily battle.

Your contribution will help support key areas related to the organization's work: education, R&D, enhanced access to treatments and clinical trials, advocacy, outreach etc.

For more information about our Support Levels: **contact us.**

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