

# JULY 2021 • NEWSLETTER



# SNMMI VI: Our Path from Molecules to the Universe

SATOSHI MINOSHIMA, MD, PhD; VALUE INITIATIVE BOARD CHAIR

We launched Society of Nuclear Medicine and Molecular Imaging's (SNMMI) Value Initiative (VI) in 2017 as a major ongoing effort to demonstrate the value of molecular imaging (MI) and radiopharmaceutical therapy (RPT) to patients, physicians, payers, and funders. The excitement around nuclear medicine and the VI initiative continues to grow and the circle of stakeholders, industry, patients, SNMMI members, and hospital administrators are increasing their engagement.

In May, the U.S. Food and Drug Administration (FDA) approved a new imaging agent for the detection of prostate cancer. Piflufolastat F-18 injection is the first fluorinated prostate-specific membrane antigen (PSMA) agent approved by the FDA and the first commercially available PSMA PET imaging agent. Therapies and other innovative imaging agents, expanding imaging capabilities are coming out in a renaissance of the field even during the COVID pandemic.

Nuclear medicine/molecular imaging and radiopharmaceutical therapy (RPT) are a result of the integration of science and technologies from a variety of areas of biomedical, physical, and computational sciences. An understanding of biological processes and diseases represents the foundation and rationale for radiopharmaceutical science. Chemistry and biology underpin the development of radiopharmaceuticals, both diagnostic and therapeutic. Our detection of signals from radioisotopes depends on physical principles and instrumentation. Complex datasets are increasingly analyzed using advanced computational algorithms including more advanced machine-learning algorithms. These tools of nuclear medicine are then applied to clinical challenges and research questions in nuclear medicine in areas of opportunity in the brain, heart, oncology and, more broadly, in human diseases. The rapid progress in science in a variety of these scientific-foundational areas

# Value Stream Mapping

MATT SHAH, VIIA CO-CHAIR AND VICE PRESIDENT, GLOBAL SALES & MARKETING, MOLECULAR IMAGING BUSINESS LINE – SIEMENS HEALTHINEERS



The Society of Nuclear Medicine and Molecular Imaging (SNMMI), in conjunction with Siemens Healthineers. conducted 15 interviews with 23 individuals across the patient lifecycle. The goal was to understand the major opportunities, as well as the risks/threats, for nuclear medicine when it comes to radiopharmaceutical therapies and determine what actions could be taken to help drive adoption and solidify nuclear medicine's role. Physicians, patient advocates, and industry leaders each provided their thoughts. To capture the findings and visually highlight the key focus areas, a Value Stream Map (VSM) was developed by Siemens Healthineers. The VSM is a business approach to document the key steps in a process and identify improvement opportunities. The learnings from all of the interviews holistically confirmed many known themes and provided a path forward on how to succeed in the future.

First and foremost, all interviewees mentioned improving patient outcomes as the biggest opportunity for radiopharmaceutical therapies. It was encouraging to see that regardless of one's perspective, the patient's well-being was front and center. Simply put, radiopharmaceutical therapies can help a greater number of people and grow the overall market. An example is in the treatment of prostate cancer, which affects a large patient population (~250k diagnosed per year in US for prostate cancer). A nuclear medicine doctor described all radiopharmaceutical therapies as a "once-in-a-decadetype of opportunity" for nuclear medicine to reshape the specialty and strengthen its role. To capitalize on this opportunity, the nuclear medicine community must adapt and further expand "the delivery model from a service provider to an integral part of patient management." This expansion would take nuclear medicine back to its roots with radioiodine over 80 years ago.

However, if nuclear medicine is not able to shift its current delivery model and play a strong role, there is a risk that other specialties will. As one nuclear medicine doctor mentioned, "there is already a push from gastroenterologists and urologists" to perform radiopharmaceutical therapies". This concern is shared from the industry as well with one CEO stating that, "if nuclear medicine doesn't drive the adoption of *Continued on page 12. See Value Stream Mapping*.

## Updated SNMMI Guidelines for Ventilation/Perfusion Imaging

RANDALL L. BURSAW, BSC., RTNM, CNMT; MANAGER, CLINICAL SCIENCES - JUBILANT RADIOPHARMA

The COVID-19 pandemic has made a significant impact on every aspect of life across the globe. Particularly in the early days of the pandemic when there was very little information available on how to protect people who were at the highest risk of exposure – our front line healthcare workers. In response, the Society of Nuclear Medicine and Molecular Imaging (SNMMI) issued a guidance on March 19, 2020, regarding V/Q lung scans and the inherent risk of the spread of COVID-19 to patients and staff related to the ventilation portion of the study.

As a result, most Nuclear Medicine departments across the U.S. opted not to perform the ventilation portion of the V/Q scan, and in many cases opted not to perform V/Q imaging at all.

As more information became available the SNMMI released an updated statement on September 3, 2020 noting that since March 2020, the COVID-19 pandemic had evolved differently in various regions of the world and, with increased availability of COVID-19 PCR testing, resumption of ventilation studies could be considered in some clinical scenarios. Since then sites have slowly been returning to performing the full V/Q scan.

More recently, on March 28, 2021, the SNMMI revised their statement again stating that V/Q imaging in its entirety is clinically necessary to help diagnose lung disease, including vascular and airway disease. These guidelines state:<sup>1</sup>

- 1. Consideration should be given to a COVID-19 PCR test, depending on local policies or institutional guidelines.
- 2. When performing ventilation studies, technologists should wear appropriate personal protective equipment (PPE) in accordance with local policies.
- 3. Airflow of the room in which the ventilation studies are performed should be evaluated, which may help to determine the required time for room turnover after the performance of a ventilation study.
- 4. The selection of the appropriate agent for the ventilation study should be carefully considered.
- 5. Local infection control groups should be engaged for guidance and to help evaluate facilities, equipment, and staff PPE necessary to safely perform ventilation studies.
- 6. The approach to performing a ventilation scan in relation to the perfusion scan (i.e. ventilation then perfusion vs. perfusion then ventilation) should be considered according to the clinical indication and consultation with the referring physician may be advisable.



Jubilant Radiopharma supports the SNMMI's most current guidelines and the use of a full V/Q imaging procedure.

There are many criteria to consider for ventilation agents. For planar acquisition Xenon-133 and for planar/SPECT acquisition Tc-99m DTPA and Tc-99m carbon labeled particles provide acceptable results. We also recommend that facilities take into consideration that that there is no 100% closed system. All aerosolized delivery systems, including carbon labeled particles, have the potential for leakage. In fact, a recent study found that 64% of subjects produced significant airborne contamination with carbon labeled particles.<sup>2</sup>

It is important to utilize best practices when performing advanced functional lung imaging. Proper administration of the ventilation imaging agent is a key factor that can contribute to the reduction of exposure to the COVID-19 virus. We advise sites to contact their nebulizer supplier to understand these proper administration techniques to ensure the safety of their staff and their patients. For more information on these techniques please visit:

<u>MediNuclear Insta/Vent™ Plus</u> <u>Bidex Venti-Scan™ IV & AeroTech™</u> Amici Swirler®

#### REFERENCES

#### 1. SNMMI Guidelines

2. C Mayes, Safe practice ventilation technique in lung scanning for pulmonary embolism, *Nuclear Medicine Communications* 2020, 41:1328–1333

An article by Jubilant Radiopharma<sup>™</sup>, a SNMMI Value Initiative Industry Alliance Leadership Circle Partner.

## The Rising Role of Radiotheranostics Supported by the Oncidium Foundation

DR. RICHARD ZIMMERMANN, PRESIDENT AND FOUNDER – ONCIDIUM FOUNDATION REBECCA LO BUE, GENERAL MANAGER – ONCIDIUM FOUNDATION

Recent research and developments have brought forward the pivotal role of Radiotheranostics for cancer care. Whether you refer to them as Radiotheranostics, Theranostics, Theragnostics, Radioligand therapy or Radionuclide therapy, they all describe an innovative approach to cancer care through a beneficial application of radioisotopes, within the Nuclear Medicine field.

#### **State of Play**

The pandemic situation did not slow down interest for radiotheranostics.

As a matter of fact, over the past 15 months, investment in new radiolabeled compounds pursued an almost exponential growth. This is not only a consequence of the very high amounts of funds presently available from investors looking for rewarding opportunities worldwide but is also proportional to the increasing awareness about the potential of radiolabeled compounds for therapy. Present decisions to invest in this area are based on the past 10 years of successful advancements. Stakeholders look at growing revenues for therapeutic drugs, certainly more attractive than for diagnostics ones.

Interest in radiotheranostics has grown over the past 20 years in the same way it did for biologics and particularly antibodies between the years 1980 and 2000. At that time, the pharmaceutical industry preferred to observe the technology evolution led by startups and smaller companies which resulted in some company shutdowns but also acquisition of the remaining ones for

Continued on page 7. See Role of Radiotheranostics.



## Delivering on the Promise of Nuclear Medicine: New Solutions for Patient Health

STEPHEN MERRICK, PRESIDENT AND CEO - NORTHSTAR MEDICAL RADIOISOTOPES

This is an exciting time for nuclear medicine. PET and SPECT technologies are providing valuable insights about the molecular structure and function of the body and disease. Theranostics and therapeutic radiopharmaceuticals are expanding with growing scientific interest and public awareness. Population growth and an aging population continue to drive demand for technologies that inform individualized patient management and treat serious cardiovascular, oncological and neurological diseases. Nuclear medicine has the opportunity to play a vital role in addressing these healthcare needs. The ability to deliver on the promise of nuclear medicine hinges upon innovative and sustainable solutions to ensure reliable radioisotope supply for patient needs and to advance clinical research.

NorthStar Medical Radioisotopes has a proven, comprehensive approach to providing such solutions. The company is the first and only U.S. commercial producer of Mo-99 and the only large-scale company in the world using non-uranium Mo-99 production processes that are sustainable and environmentally friendly.

NorthStar recognized the need for reliable domestic Mo-99 supply in a market fraught with frequent and at times prolonged global interruptions in Mo-99 availability, which result in disruptions of patients' Tc-99m diagnostic imaging tests. The company implemented a staged strategy to address the situation. First, NorthStar launched domestic nonuranium-based Mo-99 production, which was achieved in 2018 with FDA approval of Mo-99 production using neutron capture technology



State of the art hot cells containing automated equipment for filling source vessels with Mo-99 at NorthStar's facility in Columbia, MO.

and natural molybdenum. Second, NorthStar's novel platform, the RadioGenix<sup>®</sup> System (technetium Tc 99m generator),<sup>1</sup> received FDA approval to separate Tc-99m from NorthStar's Mo-99. Since becoming commercially available, RadioGenix Systems have provided more than two years<sup>2</sup> of reliable Tc-99m supply for customers, despite ongoing disruptions from overseas suppliers using legacy, uranium-based production methods.

NorthStar's approach provides an environmentally friendly, sustainable solution for Mo-99 supply. Being nonuranium based, it poses no nuclear proliferation risks nor incurs the long-lived radioactive waste and costs associated with enriched uraniumbased production methods.

Using scaled "roadmaps," NorthStar also has executed a series of RadioGenix System enhancements and processing technology advancements to further expand Mo-99 capacity and RadioGenix System efficiencies. In December 2020, NorthStar received FDA approval to use "concentrated" Mo-98, which has allowed NorthStar to begin weekly shipments of Mo-99 source vessels with activities of up to 19 Curies since early 2021. Beyond this, the Company has a Mo-99 processing facility nearing completion in Beloit, Wisconsin, to ensure reliable and increased supply of Mo-99 in parallel with continued production at the University of Missouri Research Reactor (MURR<sup>®</sup>). NorthStar is further driving production innovation with the first commercial-scale production of Mo-99 using electron beam accelerators, "concentrated" Mo-100 and the neutron "knock-out" (photo transmutation) method. Accelerator production is a highly efficient process

Continued on page 14. See Delivering on the Promise.

# Time to Shine: Radioligand Cancer Therapy Comes of Age

MIKE ROSSI, GENERAL MANAGER, ADVANCED ACCELERATOR APPLICATIONS - A NOVARTIS COMPANY



Radioligand therapy (RLT), an emerging treatment platform, may be poised to become a foundational pillar of cancer treatment.

While radiotherapy has long been a staple of localized cancer treatment, systemic nuclear medicine has generally been largely confined to diagnosis and disease assessment. Now, a class of therapeutic agents— RLT—is making exciting strides in both the clinic and the marketplace. New companies have entered this space, and the number of clinical trials studying targeted RLT in cancer has increased.

#### **Advances at AAA**

AAA is at the vanguard of targeted RLT research and development, and the company's commitment to innovation continues to move forward. A robust pipeline of RLT agents, targeting a range of tumor types, is in various stages of development. Most recently, data from the phase III VISION study, which looked at <sup>177</sup>Lu-PSMA-617 in prostate-specific membrane antigen (PSMA) positive metastatic castration-resistant prostate cancer (mCRPC) were announced and will be presented at ASCO 2021.<sup>1</sup> And two Phase 3 studies in earlier lines of mCRPC therapy are planned to start in the first half of 2021:

- PSMAfore in the pre-taxane mCPRC setting
- PSMAddition in the metastatic hormone-sensitive setting

AAA is also exploring new isotopes, such as the alpha-emitting isotope actinium-225 (<sup>225</sup>Ac) currently in a Phase 1 study in patients with mCRPC using an actinium-labelled PSMA-617. Through its investment in Aktis Oncology, the company is also developing a novel class of alphabased targeted radiopharmaceuticals to treat solid tumors.

Other targets under consideration or in early clinical programs include:

- NeoB, thought to target gastrinreleasing peptide receptor (GRPR)expressing tumor types such as breast cancer, lung cancer, and gastrointestinal stromal tumor (GIST)
- FF-10158, believed to target integrin alpha-V-beta 3 and 5 subtypes, which are particularly overexpressed on highly vascularized tumors and metastases

In addition, AAA continues to expand its pipeline strategically, with acquisitions, including recently inlicensed assets targeting fibroblast activation protein (FAP) including FAPI-46 and FAPI-74.

#### Manufacturing and Supply: A Vote of Confidence

AAA has established global expertise and specialized supply chain and manufacturing capabilities across its existing network of 4 RLT production sites, and is further increasing capacity to ensure delivery of RLT to patients in need.

In late 2020, construction began on a new RLT production site, situated close to the Indianapolis International Airport and major ground transportation hubs. This facility will initially include 4 production lines, with the capacity to expand to meet future demand.

Scheduled to open in 2023, this facility will be capable of producing up to 85,000 RLT doses annually and will ensure that AAA medicines can be manufactured, packaged, transported, and administered to patients anywhere in North America within 72 hours. In addition, AAA is expanding capacity at its existing RLT manufacturing site in Millburn, New Jersey, by 50% with the addition of 2 new production lines.

Continued on page 13. See Time to Shine.

billions of dollars, when technology maturity was reached.

Radiotherapeutics are now mature, but therapeutic development implies much higher funds than diagnostics. During the past 50 years, the radiopharmaceutical industry did not have the budget to develop such drugs in the way expected by the authorities. Only 'conventional' pharmaceutical companies had the sufficient capital to bring such drugs onto the market. In addition to their financial capacities, they also have access to a broader customer target which includes all oncologists.

As such, Bayer and Novartis became the precursors. The success of their drugs (<sup>223</sup>Ra-Xofigo, <sup>177</sup>Lu-Lutathera) is limited by their generic character and for this reason did not (yet) reach the blockbuster status (sales above US\$1B/year). Nevertheless, the next generation of drugs will all be based on proprietary assets. The first one is expected to reach the market by next year (<sup>177</sup>Lu-PSMA-617, prostate cancer – Novartis).

Besides Novartis which invested again in new therapeutic areas (FAP target, solid tumors, with iTheranostics/Sofie Biosciences -2021 or alphatherapy with Aktis Oncology), there has been a flurry of acquisitions of drugs to increase strengths of portfolios, notably the collaborations between Astellas/ Actinium Pharma, Jubilant/Sofie Biosciences, Lantheus/Noria Therapeutics, Bracco/Blue Earth **Diagnostics/Scintomics**, Fusion Pharma/Ipsen and very recently EZAG/Pentixapharm (2021). At the same time (2020), new names of startups dedicated to radiotherapeutics have appeared on the scene, such as Abscint, Abdera Therapeutics, Precirix, RayzeBio and others.

It is only recently that dedicated radiotheranostic companies have

emerged. These new companies were able to raise hundreds of millions of US\$ following successful IPO's. Telix Pharmaceutical (a company developing radiolabeled drug pairs for prostate cancer, glioblastoma, kidney cancer, bladder cancer) was a precursor, but creation of similar dedicated radiotheranostic companies was also observed such as Fusion Pharmaceuticals (solid cancers, company specialized in alpha therapies based on <sup>225</sup>Ac). Point Biopharma (created in 2020, for NET and prostate cancer, based on <sup>177</sup>Lu), RayzeBio (created in 2020, with a pipeline based on <sup>225</sup>Ac) or Precision Molecular Inc. (created in 2019 for prostate and various cancer treatments).

More than 60 radiotherapeutics have presently entered clinical trials, among which 6 are already recruiting patients in Phase III. These molecules address more than 20 different cancer indications. Unfortunately, 27 of them are targeting the very crowded areas of NET (9) and prostate cancer (18) and only a small fraction of those will reach the market. Future development should now aim at targeting alternatives indications and the choices are quite large. In oncology, radiotheranostics are not far from becoming a viable alternative to surgery, external radiotherapy, hormonotherapy, or chemotherapy, and may soon be used as second- or even first-line treatments.

The concept of radiotheranostics is generating a lot of interest, namely as it shifts from an approach where every patient is treated in the same way, to a more personalized and systemic approach, with specific radiotheranostics developed for each target. However, there is a lot of work still to be done. Next to the logistical, regulatory, financial accessibility challenges and convincing conventional pharmaceutical companies to invest in the industry, there remains an important lack of knowledge and several apprehensions among the nonnuclear physicians and the general public about their potential.

#### Accelerating Radiotheranostics Development

It is towards this goal that the Oncidium foundation was created, a non-profit, public benefit organization that would bring to light and illustrate the benefits of this technology. Based in Belgium but acting globally, the mission of the foundation is to support, promote and accelerate the development of radiotheranostics for cancer care with the aim of enhancing access for people living with cancer, regardless of origin, technology access or financial situation.

To be able to enhance Access, the foundation is determined to identify all the centers worldwide that provide radiotherapeutics for cancer care. Nuclear Medicine Practitioners can register their centers to help patients find them and evaluate therapy options. Also, through a precise and up-to-date work on Education. the foundation helps bring a better understanding of the functioning and benefits of such therapies, list marketed and under-development molecules and clear up common misconceptions. Furthermore, to build Hope, support regarding clinical developments is provided, namely with its ongoing international collaboration "Noble Registry", to enable prostate cancer patients, regardless of origin or financial situation, to access PSMA-SPECT imaging when PSMA-PET is not an option and thus, with Nobody Left Behind.

Additionally, the foundation cannot act alone and be efficient. With already 18 recognized experts on board representing 11 countries, a

Continued on page 16. See Role of Radiotheranostics.

## Clinical Care Path Defined by 360° CZT Digital SPECT/CT

15 years after revolutionizing CZT-based 3D cardiac imaging, Spectrum Dynamics leads the transformation of nuclear medicine with its VERITON-CT<sup>®</sup> digital SPECT/CT.

NILDA RIVERA, SENIOR DIRECTOR, GLOBAL MARKETING - SPECTRUM DYNAMICS MEDICAL

Transforming the nuclear medicine industry requires a true paradigm shift to bend the healthcare cost curve and improve clinical outcomes. Incremental improvements in million-dollar technology or add-ons to software simply aren't enough to achieve better and less expensive care. Fortunately, with companies like Spectrum Dynamics, with the vision, agility, and entrepreneurial spirit to bring new clinical innovations to the industry, the future looks bright for nuclear medicine and SPECT technology. In the 15 years since Spectrum Dynamics introduced the first digital Cadmium-Zinc-Telluride (CZT) based cardiac SPECT camera, it has remained focused on SPECT imaging advancements that improve the clinician's ability to guide therapy decisions and deliver better outcomes.

When Spectrum Dynamics was founded in 2000, its inventors envisioned digital CZT-based technology as a way to dramatically improve the quality of SPECT images. In 2006, it proved its theory with its D-SPECT<sup>®</sup> Cardiac Scanner, featuring its unique swiveling design and extraordinary sensitivity gains. D-SPECT<sup>®</sup> was the first major innovation in 30 years and is used today in hundreds of medical centers worldwide.

Spectrum has continuously expanded its offerings, scanner features, and functionalities to address the SPECT imaging limitations of older technology. In 2018, the company introduced the revolutionary CZT-based, 360° detector design VERITON-CT®, with a fully diagnostic, 80 cm wide-bore, high-resolution 64-slice CT — the industry's most advanced hybrid nuclear camera.

#### **Better Data Acquisition to Detect and Monitor Change**

VERITON-CT® was designed with innovations that provide

an 8 to 15 times improvement in sensitivity compared to a Nal conventional camera. Clinicians are ensured exceptional efficiency and image quality. The hybrid system's unique swiveling detector design, originated with D-SPECT scanner, transforms routine nuclear medicine.

Spectrum's proprietary **Broadview Technology** is implemented in twelve swiveling detector assemblies that move in radial and circular directions toward the patient's body to detect the exact location for imaging. The user defines the area to collect the information: organ focus or broad focus. The detectors contain proximity sensors

Continued on page 11. See Clinical Care Path.





### IBA Launches a New Cyclotron to Unlock Theranostic Radiopharmaceuticals Availability

The incredible journey of IBA [Ion Beam Application] started 35 years ago and has today changed the lives of thousands of cancer patients. At that time, a young researcher named Yves Jongen invented the "deep valley magnet" that increased cyclotrons energetic efficiency by a factor 15, something nobody believed was possible at the time.

The first prototype Yves built was a great success. This led to the creation of IBA and more importantly enabled many patients around the world to access PET and SPECT imaging modalities. A few years later, IBA pioneered another ambitious project that inspired the emergence of commercial protontherapy. This anchored IBA and its accelerators at the heart of novel technologies for cancer treatment, and established the mission of the company to protect, enhance and save lives.

But our fight against cancer does not stop there. Currently, there are still a large number of patients for whom cancer treatment fails, despite advances in science. Today, nuclear medicine is emerging as a relevant modality to address this gap by extending overall survival and quality of life for cancer patients. Theranostics and targeted therapies allow the administration of radiation directly to the targeted cells, with minimal toxic side effects to surrounding healthy cells unlike traditional modalities. The growing number of clinical trials (200+) and constant increase of new radiotherapeutic molecule developments corroborate the great potential of radioligand therapy.

To enable this revolution, we must unlock novel isotope availability and boost their production capacity. In its role, the cyclotron must be a reliable and sustainable production source of isotopes for the radiopharmaceutical industry. This is particularly the case for (Germanium-68/Gallium-68 or Ge/ Ga) and other radioisotopes such as Copper-64, for which the demand has



been constantly expanding year after year.

To address these new market needs, IBA has decided to redesign its historical Cyclone 30 MeV and create its successor, the Cyclone IKON. It is more compact and more versatile than ever.

Our engineers have developed the Cyclone IKON with 3 key features in mind:

#### 1. Versatility

More in not always better. This is particularly the case when producing radioisotopes! Injecting a pure and safe radiopharmaceutical into the patient is crucial. Hence, the optimization of the reaction energy is a key factor. Some very promising radioisotopes are actually produced at energies of ~13MeV - this avoids the coproduction of other isotopic impurities and therefore ensures the highest purity of the end-product. This specific energy is ideal for the production of Copper-64 and Zirconium-89. On the other hand, production of Germanium-68 (used for the production of Ge/Ga generators) and other SPECT isotopes (such as lodine-123, Indium-111 and Tallium-201) are typically produced around 30MeV.

Consequently, it was crucial for the Cyclone IKON to be capable of working over a large energy span (13 to 30MeV)

with full current capacity to enable the large-scale and high-purity production of emerging PET isotopes, SPECT isotopes and "parent" isotopes.

#### 2. Offering Complete Solutions

Setting up a radiopharmacy is a complex thing to do. IBA has always wanted to facilitate our customer's life from the very early stages of a project. As such, IBA is dedicated to support its customers with radiopharmacy design, equipment integration, training & GMP guidance. IBA offers complete production solutions from the target irradiation system all the way up to purified end-product. In this way, our customers have full control of their production process and know who to address for support.

#### **3.** Compactness

Space is precious. Our team of engineers has worked to reduce the size of the Cyclone IKON while still delivering high performance and reliability. We have capitalized on the successful experience of the Cyclone KIUBE to reduce the footprint of the Cyclone IKON by 20%, and its weight by 45% compared to its predecessor. The modular beam line options will allow customers to design their radiopharmacy according to their own needs and requirements.

## What I've Experienced...What I've Learned

CINDY LOVELACE, PANCREATIC NEUROENDOCRINE TUMOR PATIENT

No one is prepared for a diagnosis of cancer, but when I was told in 2011 that I had neuroendocrine cancer, I felt pretty prepared to tackle this new challenge. After all, I was a six-year breast cancer survivor and had checked the boxes for surgery, chemo and radiation therapy.

Instead, I quickly realized the knowledge I'd gained from being diagnosed with a more well known and researched cancer was not going to be enough. What hit me even harder was when my trusted oncologist told me she didn't know a lot about neuroendocrine cancer because it was so rare. Ten years later this is still a reality for many newly diagnosed patients, and there continues to be a danger that patients are under-treated or over-treated because physicians may not understand the complicated nuances of neuroendocrine cancer care or the many treatment paths now available. Treatment paths is a key understanding for the medical community because there is no one protocol for neuroendocrine patients. There are many choices, just like there are many different ways the cancer presents and progresses in each individual.

The best scenario for any newly diagnosed neuroendocrine cancer patient is to find a real neuroendocrine tumor (NET) specialist. I define a specialist as someone who treats numerous NET patients on a weekly basis and is well connected to other specialists in the NET community such as through NANETS, NET patient organizations and support groups, or an organization like SNMMI.

My search for a specialist took six months—but at first I didn't know I even needed one. I had accepted my oncologist's recommendation to have surgery to resect the small tumor found in my pancreas and the surgeon's proclamation that I was cancer-free and that no follow-up was necessary. Because my tumor was small and there was no indication it had spread anywhere else, it was assumed it had not metastasized. This is another common fallacy that patients still encounter today. My wake-up call was a news report in October 2011 that Steve Jobs had died of a pancreatic neuroendocrine tumor that had spread to his liver. I was floored. A guick internet search popped up the photo of a neuroendocrine specialist about a mile and a half down the street from my own oncologist. Who knew? Apparently my oncologist knew him and their families had dinner together often; however, his expertise as a neuroendocrine surgeon had never been discussed.

I learned another lesson—that collaboration is not a standard of practice and not necessarily encouraged in the practice of medicine in the United States. As a result, you have pockets of neuroendocrine specialists in various disciplines scattered around the country, some in large cancer centers but others in smaller private clinics, and while most of them network with one another, the medical



community at large does not necessarily know who or where they are.

My chance online search and resulting consult with a NET specialist was a life changer for me as far as my health is concerned (more below on how it also changed my career). He had been trained in neuroendocrine cancer by experts in Europe, and he opened the first clinical trial in the U.S. for the Ga 68 DOTATATE PET scan. He recommended Lenroll because of his concern that my small pancreatic tumor could have metastasized to my liver. He was right. The scan contradicted all the other "clear" scans of my liver (CT, MRI, Octreoscan) and showed two small tumors there. He predicted there would be more. He was right again. We waited about a year before my first resection and since then I've had two more, including a major debulking of my liver in 2019. I also decided to take monthly lanreotide shots for the potential of more tumor control.

Then my neuroendocrine path took another twist. Another Ga-68 scan showed very small tumors were showing up in my mesentery and uterine lining, as well as a small tumor on an ovary. Because I was being followed by a NET specialist (in collaboration with my original oncologist) I was recommended for a systemic treatment to deal with these various tumors. I consulted with a NET specialist in nuclear medicine who agreed I was a prime candidate. In early Fall 2019 and continued into early 2020, I had Lutathera PRRT with a very good initial response. While it slowed down progression for a while, I'm now taking an oral therapy as my doctors continue the systemic approach.

I currently have a team of three NET specialists, each in different disciplines and each in a dif-ferent state! Multi-disciplinary care has made a huge difference in my treatment path and my quality of life. However, I'm very

#### Clinical Care Path. Continued from page 8.

that set them as close as possible to the patient's body to provide the maximum collection of photons. Because 100 percent of each detector's surface is utilized, the VERITON-CT provides superior coverage and exceptional sensitivity that lowers the radiation doses required for both SPECT and CT up to 50%, reducing both patient and staff exposure to radiation.

The scanner was designed with the patient's comfort in mind. The axial field of view, 32cm, ensures organs such as lungs are imaged in one bed position scan. Its 80 cm bore, for both SPECT and CT, accommodates patients of all sizes. For patients worried about feeling claustrophobic, detectors will automatically pull back if they are accidentally or intentionally touched.

Spectrum Dynamics has integrated its **TruView Console** into the VERITON-CT system, providing a single platform that handles acquisition, advanced reconstruction, and quantitative post-processing of 3D data in one place for true multi-tasking and workflow optimization. Based on VERITON's care path design, the technologist can customize TruView exam parameters according to protocol and patient's needs and move bed side to utilize inroom gantry visual tools to optimize the exam based on the patient's tolerance. Unique features for efficient and consistent patient positioning include a first-of-its-kind persistence scope and bed-side interactive scan range definition.

#### More accurate data: informed decisions

VERITON's TruView Console provides advanced reconstruction algorithms only offered with PET/ CT scanners until now. Standard selections include tools to address partial volume effect, down scatter, septa penetration, and metal artifact. MIM-SD console integration provides the segmentation and analysis tools to identify lesions and quantitate key parameters for informed clinical decisions, empowering both technologists and clinicians. Thanks to the company's foresight and agility, the VERITON-CT anticipates future needs with advanced diagnostic capabilities that early adopters and researchers can deploy, such as dynamic imaging, TruFlow, or 4D SPECT/CT imaging for key applications: myocardial flow, 3-phase bone scan and renogram. The appeal of faster scans, lower doses, fully quantitative images and improved image quality offers real potential to bring more patients and studies back to nuclear medicine and pursue research opportunities.

From 2D to routine 3D imaging, Spectrum Dynamics is continuously driving new clinical applications in Nuclear Medicine, with its focus on digital technology and innovation. Its vision is to empower institutions that want to differentiate their programs in a competitive market to positively impact clinical outcomes in ways older technologies can't offer. In just 15 years, Spectrum Dynamics has led the way in innovation and has no intention of slowing down. <u>www.spectrum-dynamics.com</u>.





BroadView Technology Proprietary *swivel* head detector design provides increased sensitivity for faster scans



Total Body 3D Imaging 2m coverage: head to feet; Real-time body contouring SPECT | CT | SPECT/CT



80cm NM and CT bore Designed to accommodate bodies of all sizes



Choice of 16/64 slice diagnostic CT capabilities



TruView Console One platform, one location for clinical care decision-making: 1. Acquisition

- 2. Advanced quantitative reconstruction
- 3. Both 3D and 4D data analysis and review

#### SNMMI VI. Continued from page 1.

offers opportunities for major investments to advance clinical translation of emerging technologies in NM.

We have a "Mars Shot" to quote SNMMI's new President Richard Wahl, MD. It is Nuclear Medicine's time in the universe. As a unique field combining many scientific disciplines, advances in physics, instrumentation, and data sciences/AI, dosimetry, pharmacokinetic quantitation and more, nuclear medicine and RPT, better dosimetry, radiobiology, and high-quality clinical trials represent high-impact opportunities. These could be accelerated by major investments in the field. We will continue elevate the value of nuclear medicine and molecular imaging through the SNMMI VI efforts.

The VI's is setting its sights on some innovative

#### Value Stream Mapping. Continued from page 2.

radiotherapies, other specialties will." Another risk area is the lack of qualified personnel and infrastructure to manage the administration of new radiopharmaceuticals. With an influx of expected patients, for example with prostate radiotherapies, one nuclear medicine doctor said, "Personnel is our rate limiting factor. I'm nervous how we are going to handle prostate and we're an academic center. I don't know how smaller sites will do it." Nuclear medicine staff shortages, as well as insufficient physical infrastructure, will only be magnified as more novel therapies are introduced and in demand. The final major risk area was a perception of high costs. The overwhelming consensus from the interviews was that the discussion should always be around patient value and comparing radiopharmaceutical therapies to alternative options, not a cost discussion. A nuclear medicine doctor summarized it best by saying, "Radiopharmaceutical therapies are often thought of as expensive, but what is expensive? We need to focus on value and on quality vs. cost. When compared to other alternative therapies, they are absolutely in the same ballpark."

To drive adoption of radiopharmaceutical therapies, strong education and training (both internal and external) was the most frequently mentioned action. Internally, the community needs training on managing patients during their therapy pathways, e.g. training how to work and interact with oncologists and managing potential dose side effects. According to one nuclear medicine doctor, nuclear medicine needs to "make it clear how our therapies fit into the care of a patient and we need to be able to have data-driven conversations with oncologists as how these therapies may improve patient outcomes." Or as another nuclear medicine doctor put it, "we need to adopt the role of a 'nuclear oncologist'." Externally, there should also be focused training on nuclear medicine therapies for other specialties. One suggestion was to "start creating year-long fellowships" that enable medical oncologists to become familiar with

pathways forward including NIH-like "Study Groups"; expanding the Clinical Trials Networks to do CRO in therapies and a Radiopharmaceutical Therapy Network, and creating exciting curriculum content to awaken, inspire and develop skillsets of a much-in-demand highly trained new nuclear medicine workforce.



Satoshi Minoshima, MD, PhD Chair, SNMMI Value Initiative 2.0 Professor and Anne G. Osborn Chair Department of Radiology and Imaging Sciences University of Utah

nuclear medicine practices. Along with education and training, a strong partnership between specialties was another key recommendation. It can start small by having nuclear medicine doctors "sit and talk with oncologists at their congresses." Ideally, as one nuclear medicine physician said, it can go as far as setting up "multidisciplinary clinics with Urologists, Rad Oncs, Med Oncs, NM, etc. Then we can really move into therapy. We have to offer practices that support therapies, but also with a diagnostic background." Finally, clinical trials were identified as a top action area for the nuclear medicine community. There needs to be more data around the effectiveness of radiopharmaceutical therapies and that can be achieved through more robust clinical trial designs. A suggestion was that "all residencies should include training in clinical trial design, and courses need to be created for people who are already doing it." This training is essential as the community needs "gold standard trials to have a seat at the table."

In conclusion, the interviews showed that the nuclear medicine specialty is at an inflection point. With Lutathera paving the way and prostate on the verge of taking off, the time is now for the nuclear medicine community to adapt and seize the opportunity. By getting trained and continuing to be more involved in patient management, nuclear medicine physicians can lead the adoption of new treatments. It cannot be done alone as partnerships and multi-disciplinary teams will be essential in driving success. This combination approach will best allow the nuclear medicine to harness the power of radiopharmaceutical therapies to improve patient outcomes.



Matt Shah VP Global Sales & Marketing Siemens Healthineers Molecular Imaging

#### Time to Shine. Continued from page 6.



This commitment to invest in new manufacturing capabilities that will meet both current and future demand reflects AAA's vote of confidence in the value RLT represents to oncologists and the cancer patient community.

#### **RLT Gathers Industry Momentum**

Going forward, new alliances such as AAA's collaboration and license agreement with Artios Pharma to discover and identify novel combinations of DNA damage response inhibitors with RLT, along with the in-licensing of other new assets, may provide further opportunities for synergies within the industry, and continue to drive innovation and growth in this sector.

#### **The Road Ahead**

Worldwide, new cancer cases are expected to increase by nearly 50% over the next 20 years.<sup>2</sup> Despite medical advances, new, effective treatment options are urgently needed—especially for rare or aggressive cancers.

To help meet this need, the discovery of new targets and new radioisotopes, rapidly increasing clinical experience is leading to the broader exploration of RLT in multiple tumor types.

As additional RLT agents may be

approved, institutions may invest in capacity, offering greater access to therapy for patients. RLT, and its many potential applications in cancer treatment, will likely be an attractive field of study for nuclear medicine physicians and oncologists.

#### REFERENCES

- 1. Data on file. Novartis Pharmaceuticals Corp; March 2021.
- Sung H, Ferlay J, Siegel RL, et al. Global cancer statistics 2020: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. *CA Cancer J Clin.* 2021;71:209-249

An article by Advanced Accelerator Applications, a Novartis Company, an SNMMI Value Initiative Industry Alliance Leadership Circle Partner.

#### What I've Experienced. Continued from page 10.

aware that the best scenario would be for these specialists to all be in the same place and preferably convenient to me. I am able to travel, but many patients do not have the means or the health to travel in order to see a specialist. It's clear to me more training and more collaboration is needed in our health care system.

Here is where the career change comes in. Two years after I met Dr. Eric Liu, he and I became co-founders of the Healing NET Foundation, initially envisioning ways the non-profit 501c3 could help educate community physicians about neuroendocrine cancer. I had a personal experience showcasing the lack of communication and highlighting the need for doctors to simply KNOW how to detect and treat NET cancer, and Eric Liu had the personal experience of treating so many patients who could have had a different prognosis and/or better quality or length of life if they'd only been diagnosed earlier or received the correct treatment at the right time.

Since 2013, Healing NET Foundation has grown to encompass physician, advanced practice provider, and nurse education in CME and CE programs and we have reached out to the patient and caregiver communities to hear their stories, tell their stories, and provide resource materials written by NET patients, caregivers, and providers with experiential information on how they navigate the neuroendocrine cancer journey. We convene an annual NET Summit of invited expert physicians, advanced practice providers, nurses and researchers, as well as patients, caregivers, and industry to discuss the gaps in NET care and how they might be addressed. It's important for all stakeholders in the NET community to work together to break down those obstacles to every patient being able to receive the right treatment, by the right team, and at the right time.



Cindy Lovelace Pancreatic neuroendocrine patient Co-Founder/Executive Director Healing NET Foundation



Custom-made electron beam accelerator being placed inside NorthStar's new Accelerator Production facility in Beloit, Wisconsin.



NorthStar's radioisotope separation platform, the RadioGenix® System (technetium Tc 99m generator).

that, alongside neutron capture production, will enable multiple days of production each week, minimizing supply risks. NorthStar's first pair of electron beam accelerators were delivered in April of this year.

Diagnostic imaging studies using Tc-99m inform healthcare decisions for approximately 30 million patients worldwide annually. NorthStar and IBA (Ion Beam Applications S.A., EURONEXT) are collaborating to increase global availability of Tc-99m to meet patient needs outside the United States. The collaboration enables foreign companies to access Tc-99m Generation Systems (TCM Generation Systems) that utilize NorthStar's proprietary non-uranium based Mo-99 produced using IBA's accelerators and beamlines.

In anticipating increased needs for

therapeutic radioisotopes, NorthStar is poised to be the first commercialscale supplier of Ac-225 and Cu-67 used to deliver therapeutic radiation to destroy cancer cells in patients. Production technology limitations and limited supply have severely constrained development of these promising therapies. NorthStar is applying its expertise in commercial-scale production to provide large pharmaceutical and biotech companies with reliable Ac-225 and Cu-67 supply that will advance clinical research and make commercially available radiopharmaceutical products. The company also is collaborating with Monopar Therapeutics to develop a radiotherapeutic agent for severe COVID-19 and acute respiratory diseases.

To address the growing need for SPECT products, NorthStar is developing its SPECT radiopharmaceutical portfolio. The company has an exclusive, global licensing agreement with Capella Imaging, Inc. for a fibrin-specific diagnostic imaging agent labeled with Tc-99m. This is initially planned for imaging blood clots associated with left ventricular assist devices, and has potential applications in deep vein thrombosis and pulmonary embolism.

With a deep commitment to patients, NorthStar focuses on innovative solutions for reliable, sustainable radioisotope supply in the United States and around the world. Such efforts, in conjunction with the efforts of others in the industry, bode a very bright future for nuclear medicine and patient health.

#### REFERENCES

1. For important risk information for the RadioGenix® System version 1.2 Full Prescribing Information, click here or visit www.northstarnm.com/wp-content/ uploads/2021/05/RadioGenix-System-version-1.2-Package-Insert-Rev-04-April-2021.pdf

<sup>2.</sup> Duration as of April 2021.

### Personalized Dosimetry: "Right" for Every Patient

JOSEPH GRUDZINSKI, PhD; CO-FOUNDER & CHIEF INNOVATION OFFICER – VOXIMETRY INCORPORATED

In the *Corpus Hippocraticum*, Hippocrates wrote, "Give different ones [therapeutic drinks] to different patients, for the sweet ones do not benefit everyone, nor do the astringent ones, nor are all patients able to drink the same things."<sup>1</sup> This principle that no "one-size-fits-all" has endured the ages, but clinical adoption of this idea has been slow and rife with challenges.

For radiopharmaceutical therapy (RPT), the ability to personalize treatment by delivering "the right dose to the right place at the right time," is closer than ever. To date, most prescriptions have been essentially one-size-fits-all dosing, in part because commercial software solutions have not been patientspecific and often assumed the human body is made-up completely of water. However, thanks to an NIH strategic aim to improve RPT treatment planning, nuclear oncology will soon have more advanced precision dosing tools to improve patient outcomes with better tumor control rates and fewer normal tissue complications.

Since 2004, OLINDA has been the most utilized clinical dosimetry solution. This approach assumes a uniform distribution of activity and absorbed dose across the whole organ of a 'standard' phantom. Therefore, it does not provide dose distributions from nonuniform distributions of activity or dose gradients near tissue interfaces. While individual organ doses give population averages that may be useful for planning purposes, caution has been advised. The ICRP notes in its publication 128<sup>2</sup> that "[t]he data are not intended for therapeutic applications of radionuclides. More detailed and patient-specific



dosimetry and dose planning should be applied for therapeutic application of radionuclides."

Early attempts at voxel-level dosimetry have used kernel-based methods to improve visualization of heterogenous dose distribution. However, these methods can be inaccurate because they are often truncated and disregard tissue density heterogeneity. Truncation has significant implications for radionuclides like I-131 with relatively large gamma contributions. Not accounting for tissue density can result in inaccurate radiation transport which can be particularly important for lung and bone tumor dosimetry.

For these reasons, activity prescriptions based on OLINDA or kernel-based methods are suboptimal for delivering cytotoxic doses to targets while remaining within the tolerance dose of organs at risk.<sup>3</sup>

Advanced personalized dosimetry can overcome the challenges of OLINDA and kernel-based methods by modelling the patient's heterogeneous distribution of the drug over time using longitudinal imaging and Monte Carlo calculation of radiation transport. This combination of personalized pharmacokinetics and extremely accurate radiation transport modelling will finally enable physicians to deliver the "right" dose for each patient.

Personalized dosimetry systems currently in development promise several enhanced capabilities including automatic Region of Interest (ROI) propagation over multiple timepoints, kinetic modelling, time activity integration, and accelerated Monte Carlo dose calculations in less than a minute. The calculation speed of these emerging treatment planning systems is key to assuring personalized dosimetry fits easily into busy clinic demands without compromising confidence in the results.

A detractor to personalized dosimetry is that multi-timepoint imaging could create a cost barrier to adoption. However, cost-effectiveness studies for other common cancer therapies estimate savings from

Continued on page 16. See Personalized Dosimetry.

#### Role of Radiotheranostics. Continued from page 7.

worldwide network is emerging with Oncidium Ambassadors that endeavor to raise awareness through education campaigns, local collaborations, liaison with national cancer organizations and shared knowledge. Finally, a scientific board regrouping key opinion leaders in the field is set up to guarantee an accurate and precise communication and to identify developments and recommend projects advancing the technology.

Because radiotheranostics represent a new approach to cancer care, it comes with its set of practical challenges. Along with the development of new diagnostics and therapeutics for even more indications, the aim in the coming years will be to bring together the different actors and enable a more global use and access, so that every person living with cancer can be offered the right diagnosis and therapy, wherever and whenever they need it.

 To register your therapy center: www.oncidiumfoundation.org/register
To access the education page: www.oncidiumfoundation.org/education



Dr. Richard Zimmermann President and Founder of the Oncidium foundation



Rebecca Lo Bue General Manager of the Oncidium foundation

#### Personalized Dosimetry. Continued from page 15.

\$15,000 - \$50,000<sup>4</sup> per patient when side-effects are reduced. This is a strong indicator that personalized RPT savings will easily outweigh the additional cost of two incremental SPECT/CT or PET/CT images.

In addition, some physicians are uncomfortable asking patients to submit to multiple scans post therapy administration. While this does impose an additional burden on the patient, the inconvenience is less than other common cancer treatment inconveniences such as weekly chemotherapy infusion visits or daily External Beam Radiation Therapy (EBRT) fraction delivery. These two successful treatment regimens are evidence that patient compliance is very high when the benefit-toinconvenience ratio is high.

These are exciting times for nuclear oncology as personalized dosimetry becomes a reality and available to all clinics. These tools will empower nuclear oncologists to treat with intent. In early-stage patients, physicians can improve outcomes by increasing tumor dose and tumor control while improving quality of life by minimizing dose to normal tissues. In late-stage patients, physicians can improve quality of life through intentional disease management (not cure) or palliative intent via minimal normal tissue dose.



Advanced personalized dosimetry and treatment planning products will be important in realizing the vision of the "Right Dose" for every patient at the right time.

#### REFERENCES

- 1. J Med Ethics Hist Med 7, 6 (2014).Medline, Google Scholar
- ICRP, 2015. Radiation Dose to Patients from Radiopharmaceuticals: A Compendium of Current Information Related to Frequently Used Substances. ICRP Publication 128. Ann. ICRP 44(2S).

- 3. Int J Radiat Oncol Biol Phys Vol 109 (4), 15 March 2021, Pages 891-901
- 4. PLoS ONE 13(4): e0196007

Voximetry is a Healthtech company specializing in commercialization of complex algorithms on high-speed Graphic Processing Units (GPUs). Currently focused on radiation transport science, Voximetry is advancing personalized treatment planning in advanced stage cancer patients. Torch ™ Personalized Treatment Planning has not yet been submitted to FDA for review of its Indications for Use and is therefore NOT suitable for clinical use.

# Theranostics: Reimagining the Standard of Care

TIFFANY OLSON, PRESIDENT, NUCLEAR & PRECISION HEALTH SOLUTIONS - CARDINAL HEALTH





It may be one of the most elusive questions in all of medicine: How can healthcare providers tailor treatment to better meet the unique needs of each individual patient? Enter precision medicine and the growing field of theranostics.

Precision medicine is an area of healthcare that targets treatment for a well-defined patient population, with the goal of improving safety, efficacy and outcomes.

Theranostics take the concept of precision medicine a step further, targeting care for individual patients. In fact, the field has been called "the epitome of personalised medicine."<sup>1</sup>

How do theranostics work in nuclear medicine? Simply put, it combines a diagnostic radiopharmaceutical and therapeutic radiopharmaceutical which are tailored to the patient at the cellular level. Using specific biological pathways, a theranostic uses similar molecules to first produce diagnostic information in order to confirm the presence of a target, and then deliver a therapeutic dose of radiation to the same target. The approach is tailored based on the individual patient's predicted response or risk of disease.<sup>2,3</sup> The rationale is as simple as it is compelling: the more targeted and personalized the treatment, the better the potential outcome.

Theranostics were first developed for relatively rare conditions that could lead to serious morbidity and mortality—such as some cancers and are often used when other lines of treatment haven't been effective. In some cases, utilizing theranostics may allow some patients to avoid undergoing surgery or other more invasive treatments.

Overall, theranostics by themselves or in combination with other therapies have produced very encouraging results, including the ability to monitor treatment response and adjust it accordingly. This is particularly important with fast-progressing cancers such as glioblastoma.<sup>4</sup> As a result, some healthcare providers have been quick to adopt new theranostics.

What should healthcare providers consider as they prepare for an expanding pipeline of theranostics? First, there are robust infrastructure needs that should be carefully thought through. These include an assessment of space and shielding considerations, Radioactive Material Program (RAM) licensing, training, equipment installation and calibration, and finally, how to proceed with administration to the patient.

Providers should consider the need for dedicated space, including private and shielded patient care rooms and bathrooms. Providers should also plan for any necessary separate waste and decay storage that can handle long-lived

Continued on page 18. See Theranostics: Reimagining.





radionuclides, including active nuclides and contaminants.

There are also equipment essentials such as Positron Emission Tomography (PET) cameras, as well as the need for targeted expertise in reimbursement management, prior authorization and patient access.

In addition, a multidisciplinary team working crossfunctionally is key to a successful foray into theranostic administration. This team should include physicians (authorized users as well as medical or surgical oncologists and specialists, like endocrinologists). There is also a need to have other care team members involved (such as nuclear medicine technologists, nurses, pharmacists and radiation safety officers). When offering theranostics, there are many benefits associated with utilizing patient-ready unit doses versus standard vials from a manufacturer. Doing so:

- Ensures appropriate dosing
- Reduces operational costs
- Enhances operational efficiencies (e.g., reduced preparation time)
- Holds dose at pharmacy until patient qualification complete
- Reduces waste storage
- Decreases exposure to technologist
- Helps simplify USP <825> compliance and regulatory requirements otherwise needed for onsite dose preparation
- And finally, it allows more time to focus on patient care and safety

Theranostic radiopharmaceuticals demand justin-time supply management due to their short halflives; therefore, healthcare providers need a strategic partner who can provide reliable access and on-time delivery through manufacturing, pharmacy, and logistics capabilities, while providing resources and expertise to help navigate a complex and highly regulated environment.

What will the future hold for theranostics? Beyond their origins in oncology, theranostics may expand into earlier stages of cancer, cardiovascular and neurological indications, as well as immunology. Through better targeting, theranostics have the potential to improve quality of life, extend the life of the patient, and lower the cost of treatment. They truly could become the new standard of care.

#### REFERENCES

- 1. An introduction to the clinical practice of theranostics in oncology -PubMed (nih.gov)bjr.20180440.pdf (nih.gov)
- 2. http://theranostics.com.au/what-is-theranostics/
- 3. Stratified, personalised or P4 medicine: a new direction for placing the patient at the centre of healthcare and health education (Technical report). *Academy of Medical Sciences*. May 2015. Retrieved 6 January 2016.
- 4. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5260938/

### Value Initiative Board

THE SNMMI VALUE INITIATIVE BOARD IS MADE UP OF SNMMI LEADERSHIP, ALONG WITH CHAIRS FOR EACH OF THE VALUE INITIATIVE DOMAINS. EACH DOMAIN CHAIR IS APPOINTED FOR A TERM OF THREE YEARS.



Value Initiative Board Chair Satoshi Minoshima, MD, PhD University of Utah, Salt Lake City, UT



President, SNMMI Richard Wahl, MD, FACNM, FACR Mallinckrodt Institute of Radiology St. Louis, MO



**CEO, SNMMI and Organizational Strength and Stability Domain Chair** Virginia Pappas, CAE

Society of Nuclear Medicine & Molecular Imaging, Reston, VA



**Quality of Practice Domain Chair** Heather Jacene, MD Dana Farber Cancer Institute, Boston, MA



Workforce Pipeline Domain Chair

Christopher J. Palestro, MD Zucker School of Medicine New York







**Research and Discovery Domain Chair** John Sunderland, PhD University of Iowa, Iowa City, IA

Advocacy Domain Chair Cathy Cutler, PhD Brookhaven National Laboratory Upton, NY

**Outreach Domain Chair** Giuseppe Esposito, MD Georgetown University Hospital Washington, DC

### Volunteer Involvement by Domain

#### **Domain 1: Quality of Practice**

- Committee on Medical Internal Radiation Dose (MIRD)
- Committee on Procedure Standards
- Committee on Quality Assurance (Phantom)
- Committee on Radiation Dose Assessment Response (RADAR)
- Dose Optimization Task Force
- Oversight Committee for Guidance Documents
- Quality and Evidence Committee

#### Domain 2: Research and Discovery

- Committee on Radiopharmaceuticals
- Clinical Trials Network
- Center for Molecular Imaging Innovation & Translation
- PET Center of Excellence
- Therapy Center of Excellence
- Brain Imaging Council
- Cardiovascular Council
- Correlative Imaging Council
- Pediatric Imaging Council
- Physics, Instrumentation and Data Sciences Council
- Radiopharmaceutical Sciences Council

#### **Domain 3: Workforce Pipeline**

- Future Leaders Academy Task Force
- Academic Council
- Program Directors Committee
- Qualified Training Program Task Force
- Early Career Professionals Committee

#### **Domain 4: Advocacy**

- Committee on Government Relations
- FDA Task Force
- Committee on Coding and Reimbursement
- Third Party Payer Subcommittee
- Committee on Radiopharmaceuticals

#### **Domain 5: Outreach**

- Committee on Outreach
- Breast Cancer Imaging Outreach Working Group
- Brain Imaging Outreach Working Group
- Prostate Cancer Outreach Working Group
- Neuroendocrine Tumor Outreach Working Group
- Patient Advocacy Advisory Board

#### Value Initiative Industry Alliance Advisory Committee Chairs



James Williams, PhD CEO, Siemens Healthineers Molecular Imaging



Terri Wilson President, Blue Earth Diagnostics, A Bracco Company



Matt Shah VP Global Sales & Marketing Siemens Healthineers Molecular Imaging SNMMI would like to thank our 2020 and 2021 Value Initiative Industry Alliance member companies for their support. Together we have made incredible progress advancing patient care and precision medicine.



SOCIETY OF NUCLEAR MEDICINE & MOLECULAR IMAGING

Learn more about becoming a Value Initiative Member Company: valueinitiative.snmmi.org

### Thank You to our Value Initiative Transformative Leadership Donors

We would like to take a moment to appreciate and recognize those individuals who have donated to SNMMI's Value Initiative Transformative Leadership. As a sustained SNMMI Value Initiative Transformative Leader, you have the unique opportunity to personally support the aggressive strategies advancing the field of nuclear medicine and molecular imaging.

### Value Initiative Transformative Leadership Level (\$5,000+/year)



Giuseppe Esposito, MD, MBA Value Initiative Transformative Leader



Satoshi Minoshima, MD, PhD, FSNMMI Value Initiative Transformative Leader



Bennett S. Greenspan, MD, FACNM, FACR, FSNMMI – Value Initiative Transformative Leader



Lalitha Ramanna, MD, FACNM Value Initiative Transformative Leader



Hollie Anne Lai, MD Value Initiative Transformative Leader

### Value Initiative Principal Level (\$1,000-\$2,499/year)

• Cathy Cutler, PhD

• Vincent A. Pistilli, CPA, CGMA

#### Value Initiative Partner Level (\$100-\$999/year)

- Twyla B. Bartel, DO, MBA, FACNM
- Paresh B. Desai, MD
- Jad El Bulbul, MD
- Sharon Gleason, CFRE, ACFRE, EdD (2022)
- Paul Hamel
- Arnold F. Jacobson, MD, PhD
- Hossein Jadvar, MD, PhD, FACNM, FSNMMI

- Talakad G. Lohith, MD, PhD
- Thomas L. Marchant, CNMT
- Richard B. Noto, MD
- Bernard B. O'Malley, MD
- Alan B. Packard, PhD
- Christopher J. Palestro, MD, FSNMMI
- Scott B. Perlman, MD

### www.snmmi.org/TransformativeLeadership

# The most powerful words you'll ever hear. **\*Thank You.**

With your contribution, our profession can continue efforts leading to critical advances in cancer treatments and care.

The **Value Initiative Transformative Leadership Campaign** is the cornerstone for making these efforts a reality for patients of all ages.

### The world needs more "thank you's."

Help improve the life of a patient. Lend your support today.

### www.snmmi.org/TransformativeLeadership



SNMMI is a 501 (c)(3) tax id 36-2496678. Your donation is tax deductible as per current IRS regulations. Please remember SNMMI in your estate plans.