



## SNMMI Brain Imaging Portal to Offer One-Stop Shop for Resources

Satoshi Minoshima, MD, PhD, FSNMMI – Chair and Founder, SNMMI Value Initiative

The Value Initiative has been doing great work in Advocacy, R&D, Quality Practice, Outreach, and Workforce Pipeline. They have been successful in raising awareness and advancing the field in measurable ways. You can learn more about it by visiting [www.snmimi.org/VIResources](http://www.snmimi.org/VIResources). In the Advocacy domain, it is worth mentioning that Technegas has received FDA approval, and we have made significant progress through our work with CMS. The Centers for Medicare & Medicaid Services (CMS) have decided to remove the national coverage determination (NCD) at § 220.6.20. This means that the coverage with evidence development (CED) for positron emission tomography (PET) beta amyloid imaging will no longer be available. Medicare coverage determinations for PET beta amyloid imaging will now be made by the Medicare Administrative Contractors (MACs) under § 1862(a)(1)(A) of the Social Security Act (the Act).

It has been an exciting year for patients suffering from Alzheimer's disease and SNMMI molecular brain imagers. In 2023, a new Alzheimer's disease treatment was approved, and the national non-coverage decision for amyloid PET was lifted by CMS.

SNMMI has formed an ad hoc working group to develop and enhance the Society's Brain Imaging Portal

([www.snmimi.org/amyloid](http://www.snmimi.org/amyloid)), offering a variety of resources for members, patients, and referring physicians. The group initially focused on amyloid PET imaging. In the coming year, it will add resources related to additional modalities, including tau PET imaging, FDG PET, and dopamine transporter SPECT.

The portal provides an authoritative source for brain imaging information and training. The working group is made up of physicians, technologists, and industry members who have worked together to ensure the resources are comprehensive across the disciplines.

Among the information and tools available on the portal are:

■ **Amyloid Imaging Locator Map**—The portal's Amyloid Imaging Locator Map offers a simple way for patients and neurologists to find the imaging center nearest them. To date, 110 locations have opted to be listed on the map.

With the anticipated increased use of amyloid imaging to qualify patients for new therapies and the recent removal of the CMS non-coverage decision for the scans, the Society expects additional centers will wish to

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# NorthStar Medical Radioisotopes: Enabling Radiopharmaceutical Company Success

The exceptional promise of Radiopharmaceutical Therapy needs a robust and reliable infrastructure for radioisotope manufacture and related services.

Stephen Merrick, Executive Chairman – NorthStar Medical Radioisotopes LLC

An article by NorthStar Medical Radioisotopes LLC, an SNMMI Value Initiative Industry Alliance Principal Member Partner

We see many articles and hear many presentations which describe the potential benefits of Radiopharmaceutical Therapy (RPT)<sup>1</sup>. However these benefits are dependent on four supporting pillars:

1. Robust and reliable commercial scale manufacture of Medical Radioisotopes
2. Adequate development capacity for Patient Doses
3. Sufficient manufacturing capacity for Patient Doses
4. Efficient management of logistics for Patient Doses

NorthStar recognizes the importance of all of these foundational capabilities. With well over \$500m invested

to date, over 250 employees and a strategically located 55 acre campus, NorthStar is demonstrating that it plans to become an indispensable strategic partner for all radiopharmaceutical companies – truly walking the talk.

## Commercial Scale Manufacture of Medical Radioisotopes

The industry has seen positive steps forward with the manufacture of nca Lu-177, although there do remain concerns over supply of the target isotope material (very pure Yb-176). However, there are other promising

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*United Imaging Leads. Continued from page 12.*

With the increases in sensitivity and signal-to-noise ratio (SNR), uExcel UDP enables the reduction of partial volume effects of small lesions by increasing the matrix size and decreasing the size of each individual pixel. A higher matrix size offered by our systems results in improved spatial resolution, and with a 1024 x 1024 matrix, there are more pixels available to represent the same physical area compared to a typical PET's 256 x 256 matrix. This finer pixelation allows for better visualization of smaller structures.

The uExcel UDP is currently available on the uMI Panorama family of systems with long axial FOV ranging from 35 cm to 148 cm. This next-generation PET detector improves image resolution, reduces partial volume effects, and provides high sensitivity. This enables low dose, long delay or fast scan times for whole-body imaging. Leveraging cutting-edge technologies and a commitment to excellence, United Imaging is actively shaping the future landscape of molecular imaging with its forward-thinking approaches and state-of-the-art solutions.

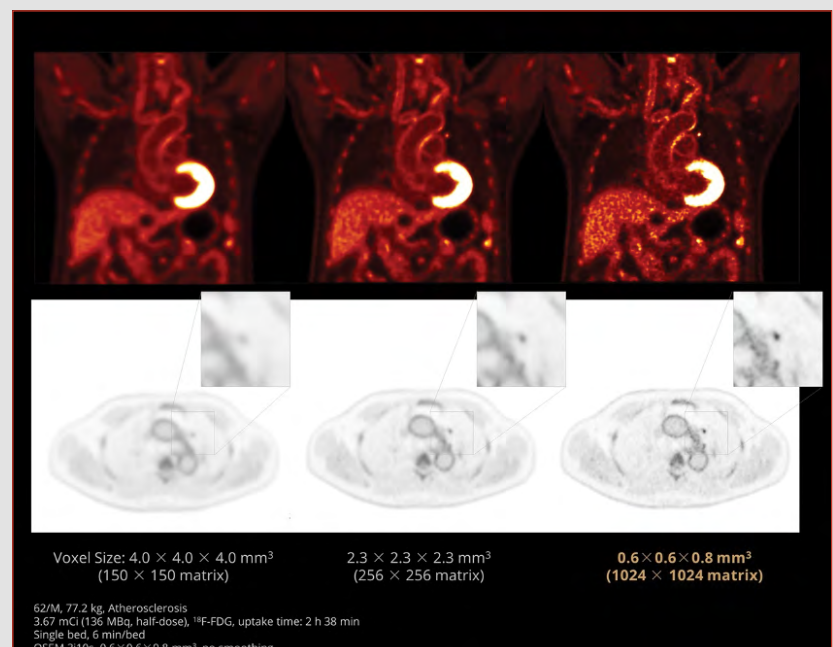


Image Courtesy of the First People's Hospital of Kunshan, JS, CHN



radioisotopes that are in such short supply that clinical trials are on-hold or progressing too slowly. NorthStar is addressing this challenge for both Cu-67 and nca Ac-225. NorthStar is already shipping Cu-67 for use in clinical trials and plans to start shipping Ac-225 in the second half of 2024. NorthStar's approaches are designed to allow scale-up as demand grows from small early stage clinical trial volumes to (hopefully) very large commercial volumes.

### Flexible Patient Dose Development Capacity

Maximizing the utility of radiopharmaceuticals needs careful selection of the targeting molecule, radioisotope and chelators/linkers to ensure that maximum binding is achieved over as long a period as practical. Using existing licensed laboratories, NorthStar is currently able to provide these services and with the completion of a patient dose development and manufacturing (or CDMO) facility at the end of 2024, will be able to offer even more extensive development facilities for multiple projects.

### Sufficient Patient Dose Manufacturing Capacity

NorthStar's 53,000ft<sup>2</sup> CDMO facility will have the capacity to manufacture patient doses for clinical trials and commercial launches. This facility will have

eight suites with scope to fit out an additional 11,000ft<sup>2</sup> depending on market needs. The radioisotopes the facility is designed to manage are Cu-64, Cu-67, Ga-68, Zr-89, In-111, Lu-177, Ac-225 and others. NorthStar also has space on its 55 acre campus to build additional facilities, including a high volume manufacturing operation.

### Efficient and Reliable Logistics

NorthStar has extensive experience with managing logistics for radioisotopes and is rapidly gaining experience with RPT patient doses, having already shipped to multiple US locations and Australia. Getting patient doses to the right place at the right time is critical for physicians and patients.

### Conclusion

NorthStar is positioned to be a leading end-to-end strategic partner for Radiopharmaceutical companies and looks forward to making very significant contributions to the success of Radiopharmaceutical Therapy and facilitating positive patient outcomes.

### REFERENCE

1. There are many different terms in use but RPT is used for consistency.



SNMMI would like to thank our Value Initiative Industry Alliance member companies for their support. Together we have made incredible progress advancing patient care and precision medicine.

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