

Advancing Research and Discovery

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Spring is around the corner, a time of renewal and growth. At SNMMI, we are focused on growing the field of nuclear medicine and molecular imaging (NM/MI) by implementing the steps necessary to achieve the goals and objectives of our Value Initiative and new strategic plan.

In the Research and Discovery Domain, chaired by Richard L. Wahl, MD, our goal is to advance the development and approval of NM/MI technologies. Research is dependent on funding. So, a key step in efforts to encourage and promote research in the field is to develop a broad-based vision document outlining the role of precision imaging and radiopharmaceutical therapy in cancer, neurodegeneration, and other medical conditions that can be used in funding requests. An ad hoc research committee (made up of experts from the SNMMI Clinical Trials Network, Centers of Excellence, Programming Committee, Council chairs, etc.) is taking the lead on this and will oversee creation of an overarching paper, as well as brochures for specific areas of interest.

Partners in SNMMI's new Value Initiative Industry Alliance will be key supporters and strategists in advancing NM/MI. Academia looks to industry to translate initial discoveries in patient care into new technology. We are also assisting members of the Small Business Advisory Alliance with their clinical trial needs.

SNMMI's Research Strategy Group is prioritizing a list of nonproprietary tracers, with the aim of moving them along the pathway to U.S. Food and Drug Administration (FDA) approval. We are currently submitting a New Drug Application for ^{18}F -DOPA for the indication of congenital hyperinsulinemia.

Getting new diagnostics and therapies from bench to clinic is an ongoing focus. For example, SNMMI is coordinating academic centers conducting clinical trials on ^{68}Ga -PSMA, and one study is nearly complete. In addition, domain members will investigate broadening the label of approved indications for ^{18}F -FDG to include infection and inflammation imaging. To that end, we will conduct a meta-analysis of published research to make the case to the FDA later this year.

To ensure that research studies published in *The Journal of Nuclear Medicine (JNM)* include all the necessary data to make a case to the FDA and support appropriate use criteria or other data-aggregating activities, SNMMI's Clinical Trials Network has developed a checklist of what to include for a paper to be considered by the journal and will write an article outlining the key components of a quality study and published paper. Having more studies that can be used to validate the efficacy of new diagnostic radiopharmaceuticals, radiotherapeutics, and instrumentation will help increase the number of FDA-approved MI agents.

Our field intersects with many others, so it is imperative that we work collaboratively—partnering with disease-specific organizations, fellow imaging societies, the National Institutes of Health, and others to advance development of imaging and therapy innovations. We will also be reaching out to hospitals to help them implement theranostics, providing guidelines covering aspects from physical space and personnel to dose handling and dosimetry.

Another tactic to streamline the development of MI agents is to develop template protocols for common MI studies, with the aim of having them adopted by the FDA and industry as the standard. A long-range objective is to have NM/MI data be an integral component of medical informatic systems. As part of this effort, we plan to create an online resource with downloadable DICOM PET/CT image sets and supporting data that will be made publicly available. Training materials on new radiopharmaceuticals will continue to be created, as well, for the NM community and referring physicians.

The end goal of all our research efforts is to improve patients' lives. The better we work together, establish support for innovative studies, demonstrate the value of new imaging agents and therapies, and communicate results—the faster we will be able to make new diagnostic and therapeutic options available.



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