The Responsibility of Success

As has often been reported in this space, several initiatives to advance molecular imaging and therapy mounted by SNM in recent years have enjoyed considerable success.

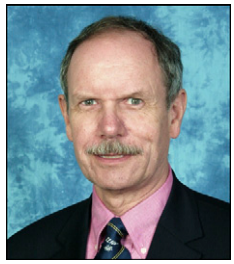
I would like to briefly recap 2 of those initiatives. First, we were successful in persuading Congress to restore funding in the Department of Energy budget for nuclear medicine research and development. In addition, we worked with the Centers for Medicare & Medicaid Services (CMS) to expand coverage of PET scans in the initial treatment strategy for patients with cancer.

This past year, we launched the SNM Clinical Trials Network to facilitate the integration, availability, and performance of imaging biomarkers into early phase therapeutic clinical trials. So far, more than 200 sites have expressed interest in participating in upcoming network trials.

It is important to note that we did not achieve these objectives on our own but as a result of strategically aligning with other medical associations, government regulatory agencies, the pharmaceutical industry, and other interested stakeholders who share our goal of making health care more effective, efficient, and available. With success comes a responsibility to ensure that these achievements are not only maintained but also built on. As SNM president, I intend to continue the collaborative atmosphere we have established and out of which we will derive our ultimate goal: more and better life-saving agents and techniques to improve patient outcomes.

Over the past several years, I have been very active in resident education, and I am concerned that we need to adapt our training programs to appropriately train molecular imaging physicians of the future. One way I have begun to do this is by working with colleagues at the American College of Radiology (ACR). We have formed a task force, chaired by me and Milton J. Guiberteau, MD, with the purpose of promoting and improving nuclear medicine training and, ultimately, attracting more medical students to the field. We recently met to begin to identify strengths and weaknesses of existing nuclear medicine and radiology training programs. We are now examining recent surveys of current training pathways and will be reporting soon on suggested ways to develop new programs or enhance existing ones. Clearly, both SNM and ACR will benefit as better-trained and qualified physicians, scientists, and technologists rise through our ranks.

Another instance of SNM's efforts to bring groups together and provide services to our members, the broader community, and our patients is a recent affiliation with the International Partnership for Critical Markers of Disease (CMOD) to promote discussion among various stakeholders—such as the U.S. Food and Drug Administration (FDA), pharmaceutical manufacturers, and the imaging community—to facilitate the integration of imaging biomarkers into clinical trials.



Michael M. Graham, PhD, MD

As we have begun to address the organizational details needed for the Clinical Trials Network, SNM has heard from a diverse group of industry and medical practitioners of a real interest in and need for information about current good manufacturing practice (cGMP); chemistry, manufacturing and control (CMC); and associated regulatory issues for manufacturing PET radiopharmaceuticals. Recognizing that SNM is uniquely positioned to explain and define the role of centralized investigational new drugs (INDs), such as ^{18}F-FLT, and the ways in which they will enable the development of investigational new PET imaging agents for use as biomarkers in multicenter therapeutic clinical trials, it is important that we actively seek out opportunities to share this knowledge.

At SNM's Midwinter Meeting in Clearwater, FL, we held a 2-d workshop devoted to the Clinical Trials Network. One of the most active sessions was with the radiopharmaceutical manufacturers, who had many questions and concerns about the details of supplying agents for the clinical trials. In May, we held a second meeting in the same area of interest in collaboration with CMOD on the campus of the National Institutes of Health. At that meeting, SNM and CMOD surveyed the regulatory history of PET, reviewed current guidelines for PET compounding, and addressed the critical necessity of developing new tracers and radiopharmaceuticals in compliance with the FDA's cGMP and CMC regulations. We also continued to address the need for harmonization and standardization across multiple imaging sites and discussed the concept of a centralized IND and the importance of both of these to SNM's new Clinical Trials Network.

Because CMOD was established to accelerate the identification, validation, and appropriate application of biomarkers in cardiovascular and related diseases, joining with them to delineate and disseminate these issues and to find solutions to these challenges is a responsibility shared. Success in this arena will pave the way for success in SNM's clinical trials initiative.

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hospitals hire professionals with high levels of training, such as nurse practitioners and physicians, and that will be expensive."

University of California at Los Angeles

SNM Clinical Trials Network Support Grows

On May 14, the SNM Clinical Trials Network, an initiative designed to address the need for streamlined drug discovery through the integration of imaging biomarkers into multicenter clinical trials, announced the addition of Genentech, Inc., as a supporter. SNM launched the Clinical Trials Network in late 2008 to facilitate more cost-effective drug development through the integration and standardization of imaging biomarkers into phase 1, 2, 3, and 4 therapeutic clinical trials. As part of this initiative, the society continues to bring together pharmaceutical developers, the imaging community, biomarker manufacturers, and regulatory agencies to address critical needs for biomarkers in multicenter trials. A formal introduction to the Clinical Trials Network was held at a 2-d workshop in Clearwater Beach, FL, in February, and educational sessions about the network were presented in June at the 56th SNM Annual Meeting in Toronto, Canada.

"We are gratified to have Genentech—a pioneer in the field of developing targeted therapeutics—join us in this important endeavor, which we hope will broaden the scope and effectiveness of today's medical practice and lead to improved patient care in the near future," said Peter S. Conti, MD, PhD, cochair of the SNM Clinical Trials Network. "We are pleased that such an innovative corporate leader supports our mission of advancing molecular imaging and therapy."

More information about the SNM Clinical Trials Network, including latest news about participants, is available at: www.snm.org/clinicaltrials.

SNM

Gerald Denardo, MD, Retires

Gerald DeNardo, MD, professor emeritus of internal medicine and radiology at the University of California (UC), Davis, recently notified friends and colleagues of his retirement from his UC position to pursue a range of personal and professional interests. With his wife, Sally J. DeNardo, MD, he pioneered the federally funded radioimmunotherapy (RIT) program at UC Davis. Gerry's long career has paralleled that of clinical nuclear medicine, from early scintigraphy studies to sophisticated combined molecular imaging and therapy. In 1985 the DeNardos treated their first patient with non-Hodgkin lymphoma—the first in the United States to undergo RIT for lymphoma. "Our program has generated a series of novel nanomolecules and related platforms and insights with considerable potential," he said. "For about 50 years, I've had a thrilling ride, growing, building, learning much and translating from bench to bedside with the help of many others." His work has been marked by ingenuity, inventiveness, and consistent compassion and good humor. Both the DeNardos have received wide acclaim and honors for their work, including the 2000 Cassen Award from SNM. The Newsline editor congratulates Gerry on his extraordinary career and looks forward to hearing about his new and diverse endeavors.

Conrad Nagle, MD
Editor, JNM *Newsline*

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The SNM Clinical Trials Network is seeking to register more than 200 sites and is beginning to qualify registered sites using SNM's successful phantom imaging program. We intend to standardize image acquisition capabilities at a large number of sites so that they will be able to efficiently incorporate quantitative imaging of biomarkers into therapeutic clinical trials. The network is also in the process of registering radiopharmaceutical production sites—both commercial and academic—that can supply the necessary radiopharmaceuticals. The first agent to be produced in this uniform manner will be ^{18}F-FLT.

Finally, it is becoming increasingly clear that we, the nuclear medicine community, need to publish a series of high-quality papers examining cost effectiveness and comparative effectiveness in order to appropriately inform the rest of the world—referring physicians, regulatory agencies, CMS, and insurers—that molecular imaging procedures should be more widely utilized. To accelerate this effort, I intend to create a task force in the upcoming months to develop high-quality, comparative effectiveness studies. A unique opportunity has been presented by President Obama's directive that the Institute of Medicine define the ways in which it will spend $1.1 billion on such studies as part of the stimulus package. This is a great opportunity to develop high-quality retrospective, metaanalysis, and prospective studies and should be particularly attractive to young medical professionals. This is an area that you will be hearing more about in the months to come.

It is my hope that the students and young physicians and scientists we assist and the initiatives we undertake will one day usher in more capable and cost-effective imaging techniques and practices in laboratories and clinics around the world. It is a future that looks increasingly achievable because of the initiatives we are undertaking today.

Michael M.Graham, PhD, MD
SNM President