

Molecular Imaging: The Future of Modern Medicine

The second Industry/Expert Molecular Imaging Summit, “Molecular Imaging: The Future of Modern Medicine,” was held February 17–19 in Newport Beach, CA. Hosted by the SNM Molecular Imaging Center of Excellence (MICoE), the meeting provided an opportunity for leaders from academia, industry, government, and regulatory agencies to come together both formally and informally to identify and discuss issues crucial to the advancement of molecular imaging along the continuum from discovery to beneficial clinical applications.

A Look Back

This summit was part of a series of workshops, conferences, and retreats targeted at developing a unified community approach to issues in molecular imaging and therapy and was a direct follow-up to July 2006 and June 2007 conferences addressing emerging technologies and important action items.

The July 2006 Molecular Imaging Summit took as its title “Shaping the Future” and focused on 5 broad topics: drug discovery, clinical issues, basic research issues, instrumentation and animal models, and standardization and education. The 3 themes that defined issues emerging from presentations and discussion groups were standardization, multidisciplinary education, and cooperative change and management. These were then addressed with a lengthy list of suggested action items for future consideration. The complete proceedings of the summit appeared in *Newsline* (*J Nucl Med.* 2006;47[12]:15N–63N).

Many of these action items were addressed at the June 2007 meeting, called “Developing Strategies for Imminently Emerging Technologies: An Action Planning Retreat” (*J Nucl Med.* 2008;49[2]:37N–40N). Participants in the retreat identified key issues in emerging molecular imaging technologies, including topics related to: (1) development and clinical introduction; (2) regulatory actions; and (3) Centers for Medicare and Medicaid Services (CMS) funding, clinical acceptance, and expansion of indications. Action steps were recommended for SNM and other groups, including: (1) demonstrating the clinical effectiveness of molecular imaging; (2) ensuring reimbursement for use of molecular imaging agents; (3) obtaining U.S. Food and Drug Administration approval based on validation rather than on clinical results; (4) improving standardization efforts, including the development of community guidelines; and (5) addressing intellectual property issues.



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At the 2008 Molecular Imaging Summit

The recommendations and action plans specified at previous meetings informed the selection of speakers and the content of sessions at the 2008 summit, the proceedings of which are summarized here. Our goal at the summit was to build on previously identified action items by developing specific tactics and tools that could be taken back to the MICoE for incorporation into a range of activities.

The program for the 2008 summit was organized specifically to encourage discussion and feedback from participants. The 4 main sessions included “Strategies to Engage Pharma,” “Strategies for Fast-Track Technological Development and Regulatory Issues,” “Strategies to Engage Referring Physicians and Increase Utilization of Clinical Molecular Imaging,” and “Strategies for Getting the Word Out.” These sessions provided a framework that was augmented by question-and-answer periods, break-out sessions in which participants informally discussed issues, and a wrap-up presentation in which each session chair reported conclusions and recommendations.

In the separate sections that follow in this issue of *Newsline*, each of the session chairs summarizes the topics discussed, challenges identified, and recommendations presented for consideration. Edited versions of the session presentations follow. In addition to suggesting action items for the SNM and MICoE, we are confident that this document will also provide valuable consensus guidance and substantial food for thought for the entire molecular imaging community.

Featured Speakers

The 2008 summit in Newport Beach was fortunate to have 3 noted featured speakers, each of whom brought a different perspective on the significance of molecular imaging and its potential for revolutionizing diagnosis and therapy.

Mauro Ferrari, PhD, a founder of biomedical nano/microtechnology applications, delivered the keynote ad-

dress in the opening session of the summit on February 17. He is professor and chair of the Department of Biomedical Engineering at the University of Texas (UT) Health Sciences Center at Houston, professor of experimental therapeutics at the UT M.D. Anderson Cancer Center, professor and director of the Center for NanoMedicine at the Brown Foundation Institute of Molecular Medicine, professor of engineering at Rice University, and president of the Alliance for NanoHealth (all in Houston). In addition to clarifying for us the many definitions currently applied to nanomedicine, Ferrari described the engineering and geometry that can enable a single particle to carry multiple therapeutics and diagnostics and to release these at precise timepoints within well-defined targets. He emphasized the importance of infrastructures that span institutional and geographic barriers as essential to sharing data and thereby accelerating discovery and development.

Nancy Januszewski, from the Lymphoma Research Foundation (LRF; Plainsborough, NJ), provided the opening address on the second day of the summit, with insights from the perspective of a 7-year survivor of non-Hodgkin's lymphoma. She has testified before the U.S. Congress and is a regularly invited participant in the American Association for Cancer Research annual Scientist-Survivor Program. Her address not only put a personal face on the experiences of the lymphoma patient but highlighted the hopes that patients have for molecular medicine and the power of dedicated advocacy by all participants in the health care matrix.

Jonathan Alter, an award-winning *Newsweek* columnist, television analyst, and author, presented the February 18 luncheon address. His 2007 article on CMS reluctance to reimburse for radioimmunotherapy (RIT) and the corresponding reluctance of some oncologists to refer their patients for RIT brought much-needed focus on the potential benefits of a range of radiolabeled therapeutic regimens. In addition to discussing his research on RIT issues, Alter spoke about his personal experience with lymphoma and the ways in which this experience informs his reporting on medical and health care issues.

An Update on the Bench-to-Bedside Campaign

The many issues identified at the 2008 Molecular Imaging Summit can be addressed only through the concerted efforts and dedicated support of all members of the molecular imaging community. It was for this reason that the SNM Bench-to-Bedside Campaign was initiated in 2006. With an original goal of raising \$5 million to support this effort, we are pleased to note that as of February 2008, corporate and individual gifts and pledges totaled \$4,317,241, with more pledges expected in the coming months. We are especially gratified to see that not only have large industry companies stepped forward to support the campaign but startups also have contributed, clearly recognizing the importance of the proposed initiatives for their success and advancement. As of February, our donors at various levels included: Corporate Circle (\$500,000+): GE Healthcare,

Bristol-Myers Squibb Medical Imaging, IBA Molecular, Siemens Medical Solutions USA, and Covidien (formerly Tyco Healthcare/Mallinckrodt); Corporate Visionary (\$250,000-\$499,999): Cardinal Health, Philips, MDS Nordion, and Bracco Diagnostics; Corporate Contributor (\$50,000-\$99,999): Molecular Insight and Mediso Medical Imaging Systems; and Corporate Friend (\$5,000-\$49,999): FluoroPharma, Digirad, and Rotem.

The Education and Research Foundation (ERF) of SNM is responsible for seeking individual and member participation in the campaign, with a goal of raising \$500,000. By the end of 2007, the ERF had raised more than \$136,000 in gifts and pledges and reported several major gifts under consideration.

An Update on the SNM MICoE

The SNM MICoE takes as its overarching goal the implementation of molecular imaging and carries out this goal through a 5-point strategic plan: (1) providing indispensable resources for education, knowledge exchange, training, and networking; (2) advocating for molecular imaging and therapy; (3) educating and promoting collaboration with referring physicians and patient groups; (4) supporting innovations in translational research; and (5) positioning molecular medicine as an essential tool in providing the highest standards of patient care around the world.

Nine MICoE task forces are currently at work pursuing various aspects of these goals. Specific cooperative successes in the past year have focused on arriving at a community consensus definition of molecular imaging and its associated techniques and in enhancing avenues and methods of communication about important molecular imaging topics. Other successes have been seen in cooperative advocacy actions, part of a continuing strategy to proactively lobby for reimbursement and research funding. MICoE task forces have also been active in outreach, working to bring representatives from clinical practice, research, the pharmaceutical industry, other professional societies, and patient perspectives together to discuss potential areas of collaboration. Other notable achievements have been made in enhancing educational content at SNM meetings, developing a molecular imaging curriculum for residents, initiating a molecular imaging speakers bureau, instituting more grants and awards, conducting surveys on PET utilization that can inform the development of clinical practice guidelines and identify research priorities, and participating actively in efforts to improve cross-site comparability and validation of PET data to support expanded multicenter trials.

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(Continued on page 20N)

(Continued from page 17N)

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