

SNMMI Leadership Update

62nd Annual Meeting

Southwest Chapter of the SNMMI

Houston, TX

April 1, 2017

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SNMMI President

SNMMI Leadership 2017



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SNMMI Strategic Plan – Approved June 2013

- Goal A:** Advance the development and approval of nuclear medicine and molecular imaging technologies.
- Goal B:** Facilitate and support the availability and clinical utilization of nuclear medicine and molecular imaging technologies.
- Goal C:** Increase appropriate utilization of radionuclide therapy.
- Goal D:** Advance and promote quality, value and safety of molecular imaging and nuclear medicine.
- Goal E:** Support and enhance the professional workforce and environment.

Goal A

Advance the development and approval of
nuclear medicine and molecular imaging
technologies

SNMMI FDA Task Force

Mission:

To create a more efficient and timely FDA approval process for new and non-proprietary radiotracers and radiotherapeutics.

Strategic Plan:

- Optimize evidentiary requirements for the approval of new radiotracers and radiotherapeutics.
- Engage FDA in dialogue on our recommendations to improve approval process.
- Improve clinical access and reimbursement for non-approved agents under development (traditional IND) or under an expanded access IND.

Recent Activities:

- The Task Force met with FDA staff at the SNMMI Annual Meeting in San Diego to continue the discussions held last December. The discussion centered on ways in which evidence might be harmonized for approvals at FDA with coverage decisions at CMS.
- The Task Force is planning a stakeholder meeting in the spring of 2017 to include FDA, CMS, NRC, medical societies and industry partners to discuss evidence and approval and coverage pathways.
- Fluciclovine F18 (Axumin®), was approved in May 2016 by the FDA for PET imaging in men with suspected recurrence of prostate cancer based on PSA following prior treatment. Ga68 NETSPOT was approved in June 2016 for imaging of somatostin expressing tumors in adults and children.

Increase Translation of New Technologies and Agents

Translation and Preclinical Imaging Workshops

- 3rd AACR-SNMMI Joint Conference on “*State-of-the-Art Molecular Imaging in Cancer Biology and Therapy*” is being planned for February 2018 in San Diego, CA.
- 3rd *Theranostic World Congress on Ga-68 and PRRT*, March 12-14, 2015, at Johns Hopkins University in Baltimore; a jointly sponsored meeting focusing on imaging with Ga-68 and theranostic agents.
- “First-in-Human” continuing education session took place on January 28, 2016, at the Mid-Winter Meeting.
- Sessions at the 2016 Annual Meeting include “Theranostic Nanoparticles,” “New First-in-Human Optical Tracers,” “PET/MR I: Technical Advances,” “PET/MR II: Clinical Applications,” and “Molecular Imaging of Infection and Inflammation.”



SOCIETY OF
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SNMMI Clinical Trials Network (CTN)

Vision

The CTN will take a leadership role in advancing the use of molecular imaging and radiotherapeutic agents, optimizing their use in clinical trials for translation and dissemination into clinical practice.

Mission

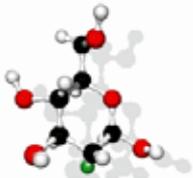
Facilitate the effective use of molecular imaging in clinical trials through standardization, coordination, and education for drug development and regulatory approval.

Growing Molecular Imaging

- Through the approval of new radiopharmaceuticals (assisted with Axumin and NETSpot)
- High-quality clinical trials, including trial design and drug development consultation
- Improving standardization of the entire imaging process
- Providing access to high-quality imaging resources

Tools and Methods

Welcome to the
Clinical Trials Network
Database System



Database

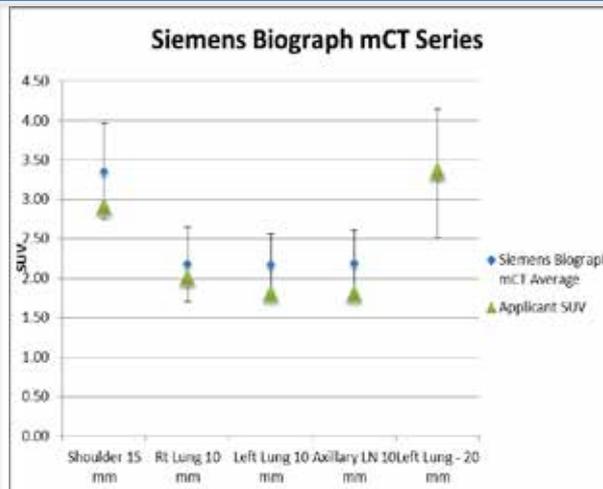
hosts a wealth of data on manufacturing and imaging sites world-wide: equipment-personnel-research experience-RP's used

Education

comprehensive curriculum relevant to entire NM community; global outreach to promote MI research and advance drug development



DaRT - links with the CTN database to search site and RP availability; share data to promote RP development; aid pharma in study site selection



Standardization

ensure scanners are quantitatively accurate/remain stable during a study; harmonize imaging methods across models

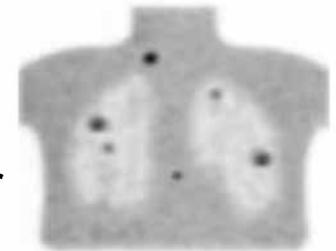
CTN: Gallium-68 Labeled Radiotracers

- Users group members met with FDA officials to discuss the approval pathway for the manufactured Ga-68-labeled drugs, kit-based drugs, and generators.
- SNMMI/CTN co-sponsored the 3rd Theranostic World Congress on Ga-68 and PRRT in March 2015.
- These activities have contributed to the rapid regulatory advancement of these agents within FDA.
- CTN is now organizing Ga-68-PSMA trials for primary and biochemical recurrent prostate cancer imaging.

Clinical Trials Network

Ensure standardized, quality PET imaging in clinical trials for drug development and of new radiotracers

- Scanner Validation Program – oncology chest phantom has validated more than 290 scanners on four continents
- Assisted with 9 industry-sponsored trials
 - Using FDG, FLT, FDHT, F-choline and 2 proprietary agents
- Co-sponsored a workshop with NCI titled ‘Immune Modulation Therapy and Imaging’ to identify ways to image response to therapy for immuno-oncology agents
- Developed reader training for two new agents:
 - F-18 Fluciclovine (Axumin®) for Blue Earth Diagnostics (including DICOM cases)
 - Ga-68 DOTATATE (NETSpot®) for AAA



Goal B

Facilitate and support the availability and clinical utilization of nuclear medicine and molecular imaging technologies

Mo-99 Supply – SNMMI Advocacy

- On September 12, 2016, The National Academy of Sciences released its long awaited report on *Molybdenum-99 for Medical Imaging*. The Report found that there is a greater than 50% chance of a severe shortage in the next couple of years. Today, the manufacturers and reactor owners are in a much better position to manage any shortages.
- Submitted comments to the OECD on the Security of Supply of Medical Radioisotopes and presented to the high-level working group (HLG-MR) in Paris.
- Continued participation in the White House working group on Mo-99 supply, which meets quarterly with OSTP, NNSA, FDA, CMS, and NRC. SNMMI presented at multiple meetings.
- SNMMI members and patient advocates met with more than 100 Congressional offices this year to advocate for a domestic source of Mo-99.

SNMMI Outreach Program – Creating Partnerships with Patient Groups and Referring Physicians

Goals:

- Educate patient advocacy groups about the current value and future promise of molecular imaging and prepare them to be powerful allies in maintaining and expanding access to molecular imaging and therapy.
- Increase knowledge among referring physicians about current value and future promise of molecular imaging.

Patient Groups – Allies in the Era of Patient-centered Medicine

- **Patient Advocacy Advisory Board**

Eleven major patient advocacy organizations that advise us on patient-specific program development.

- **Programs:**

- Patient Portal: Patient-focused website to explain molecular imaging and therapies for each disease.
- SNMMI Hill Day, May 1, 2016: accompanied by SNMMI members, patient deliver a powerful message about the value of NM and MI.
- Fact Sheets: Modality- and disease-specific brochures in print and online, 8 fact sheets now available in Spanish.
- Interactive Webinars: Allow patients to learn more and ask questions.
- Patient Education Day: Patient-focused track at our Annual Meeting; overview of nuclear medicine and breakout sessions (120 attendees).

Creating Partnerships with Referring Physicians

- Expert working groups with referring physician members
 - Targeted Radioisotope Therapy Outreach
 - Brain Imaging Outreach
 - Prostate Cancer Outreach
 - Bone Scan Outreach
 - HIDA Outreach
 - V/Q Outreach
 - PET/CT for Restaging of Malignant Disease Outreach
- Additional working groups will be created as needed

Creating Partnerships with Referring Physicians

- **Referring Physician Initiatives**

Disseminating information about new technologies and recently developed AUCs via:

- **Joint sessions** with referring physician societies
- **Road shows** to reach local physicians unable to attend national meetings (free CME)
- Disease-specific **webinars** with speaker duo – NM and referrer (free CME)
- Updates to the Healthcare Provider audience page planned for the coming year

Disseminating Newly Developed AUCs

- New outreach working groups established to develop strategic dissemination plans for AUCs:
 1. Bone scintigraphy in malignant disease
 2. Hepatobiliary scintigraphy in abdominal pain
 3. Ventilation/perfusion imaging in pulmonary embolism
 4. FDG-PET/CT for re-staging malignant disease
- Additional working groups will be created as needed

Goal C

Facilitate and support the availability and clinical utilization of radionuclide therapy

Increase Appropriate Utilization of Radionuclide Therapy

- Advocate for the regulatory approval and reimbursement of emerging agents.
- Advance the use of approved agents
 - Radium-223 Cl_2 and radioimmunotherapy
 - NCI/SNMMI workshops on Targeted Radionuclide Therapy (March 2013, October 2014)
 - Roadshows on radionuclide therapy planned
 - Online education modules
 - Patient brochures on available therapies
 - Webinar series for referring physicians

Increase Appropriate Utilization of Radionuclide Therapy, cont.

- **Educate nuclear medicine and referring physicians**
 - SNMMI AM 2016 Categorical on “Imaging and Therapy of Neuroendocrine Tumors”
 - **Online modules** for Maintenance of Certification to cover samarium/strontium, Ra-223, I-131, MIBG, PRRT, and RIT
 - **Joint sessions at:**
 - American Thyroid Association – 9/22 on the utility of pre-treatment scans and 9/23 on I-131 for Distant Metastasis;
 - American Society of Radiation Oncology – 9/27 on Radionuclide Therapy
 - North American Neuroendocrine Tumors Society – on 10/1 on Updates on imaging techniques and PRRT for NETs
 - ASCO GI - on 1/20/17 on Practical Aspects of PRRT: What you really need to know about PRRT and its risks

NEW Therapy Center of Excellence

- Launched in Spring 2016
- Brings together a centralized group of all constituents within this area, creating a multi-disciplinary interest group whereby industry, big pharma, physicians, scientists, government and regulatory agencies as well as other stakeholders can convene to share ideas, develop education offerings and advance the utilization of radionuclide therapy.
- **Purpose**
 - Provides a forum for members with similar interests
 - Provides expertise in TRT
 - Fosters research and education in TRT
 - Provides outreach to other professionals and organizations

Committee on Radioiodine Theranostics (CORT)

- To educate, develop, and promote the appropriate use of radioiodine theranostics.
- To facilitate appropriate research of radioiodine theranostics.
- To encourage the participation of nuclear medicine physicians in the issues involving radioiodine theranostics such as guidelines.
- To encourage collaboration with our European and Canadian colleagues in the specialty of Nuclear Medicine regarding radioiodine.

Differentiated Thyroid Cancer: International Harmonization Initiative

- **SNMMI, EANM and ATA Collaboration**
- Focus is on the management of differentiated thyroid cancer in order to improve patient management by harmonizing the understanding of best practices in a collegial manner.



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Goal E

Support and enhance the professional
workforce and environment

Women in Nuclear Medicine (WINM)

- Purpose:
 - promote women physicians and scientists in nuclear medicine and molecular imaging;
 - foster the development of professional interests
 - address problems encountered in the practice of nuclear medicine: promoting leadership and career development in women
 - raise awareness of scientific contributions of women in nuclear medicine: recognizing the challenges of balancing career and family
 - promote fair and equitable treatment, and improving the climate for women in nuclear medicine in all stages of their careers.
- 2nd Annual Afternoon Tea – was held during the 2016 San Diego Annual Meeting – 120+ participants
- Special Event being planned for MWM2017 – in conjunction with the Curie Fund for Women in Leadership through the ERF

Professional Workforce and Environment

- Provide education to promote best practices, review current research, and understand emerging technologies and their applications:
 - 250+ CE sessions and scientific presentations at SNMMI meetings annually
 - Large catalog of online CE courses delivered through the SNMMI Learning Center
 - Live webinars offering CE credit and SAMs on a variety of topics throughout the year
 - JNM/JNMT CE articles available in the Learning Center
 - MOC activities for physicians to support both Self-Study (Part II/ SAMs) and Practice Improvement (Part IV) requirements delivered in live and enduring formats

PET/MR Credentialing Task Force

- American College of Radiology / SNMMI joint effort
- Co-chaired by Rathan Subramaniam, MD, PhD, from ACR and Hossein Jadvar, MD, PhD, from SNMMI
- Published April 2015 – *ACR/SNMMI Approve Joint Credentialing Statement for PET/MR: Brain*
- Full body PET/MR – due out Spring 2017.
- Next Focus – Cardiology – due out Fall 2017.

2018 SNMMI Future Leaders Academy

- Next Academy – 2018 in Orlando, FL
 - Deadline for Applications is September 1, 2017
- Eligibility
 - Must be a current resident, fellow, or in-training scientist; OR
 - Must be within the first 7 years after residency or training completion, post-doctoral training or nuclear pharmacy training AND
 - Must be a member of the SNMMI for at least the past year (2016-2017)

Council/Center Internship Program

- Created several years ago to involve young professionals in SNMMI at the council and center levels
- Participate in board meetings, assigned projects, provided travel support
- Each council/center (13) selects one intern for a 2-year term
- New interns will begin their terms in June 2017 – final selection process is currently underway.

Thank you!
Questions?

