The SNMMI Therapy Center of Excellence (Therapy CoE) aims to advance the utilization of targeted radioisotope therapy through education and collaboration with other organizations and stakeholders. Therapy CoE will be a repository of expertise and knowledge, to advise and augment organizations within SNMMI which are working on issues related to targeted radioisotope therapy.

**SNMMI Value Initiative 2.0 – Engagement of Councils and Centers of Excellence**

In 2018, SNMMI launched its Value Initiative – a comprehensive strategic plan to advance the crucial role of nuclear medicine and molecular imaging in patient care and science ad discovery. The next step will become SNMMI’s Value Initiative 2.0. As part of Value Initiative 2.0 SNMMI will continue to adjust our organization to the changing health care environment. Value Initiative 2.0 will also engage as many SNMMI members as possible through the work of various committees, working groups, SNMMI councils and centers of excellences and the SNMMI chapters.

As part of this inward focusing effort, councils and centers of excellence will be participating in Domain conference calls and working directly with the chairs from the six (6) domains to address the opportunities and develop strategies to meet them.

As a center of excellence, the Therapy CoE will be involved in every domain; Quality of Practice, Research and Discovery, Workforce Pipeline, Outreach, Advocacy and Organizational Strength and Stability.

**Goals and Programs for FY2020**

Therapy CoE intends to focus its efforts in the next couple years on initiatives which support patients maintaining access to effective therapeutics, administered by trained practitioners who are part of an integrated health care team. Issues Therapy CoE will address through educational and outreach initiatives include identifying challenges to utilization of therapeutics, education of referring physicians, and reimbursement. Additionally, Therapy CoE will promote partnerships for multicenter retrospective studies of existing therapeutic models. Specific goals and objectives include:

1. **Committee on Radioiodine Therapy (CORT)**
   a. Managing SNMMI’s participation in the second Multilateral Conference on Differentiated Thyroid Cancer and thyroid disease, scheduled for March 2019
   b. Presentations at other organizations, such as the Thyroid World Congress
   c. Conducting a survey to establish a database of facilities perform dosimetry to help determine the prescribed activity of I-131 for I-131 therapies for patients with differentiated thyroid cancer.

2. **Theranostics Consensus Conference**

   The Therapy CoE is collaborating with CTN and NCI to organize a two-day symposium in November 2019 which will address: Current State of Theranostic Technology and Challenges; Trial Design; Reimbursement; and Training. Invitations will be extended to academics, clinicians, industry and regulators; the variety of stakeholders in Theranostics.

   In addition, the Therapy COE will be collaborating with the Quality Committee to organize a Nuts & Bolts conference in October 2019. The SNMMI Theranostics Conference includes topics such as: therapies, theranostic, building your radionuclide clinical practice and more.

3. **ASTRO/SNMMI Task Force on Theranostics**
   The Therapy Center will continue efforts with ASTRO on the joint Task Force. Specifically, the two working groups (care pathway/workflow and training and education requirements) will continue to meet via conference call with the goal of having draft white papers available by next spring.

4. **Theranostics Tool-Kit**
   The Therapy Center of Excellence discussed the Theranostics Tool-Kit during their retreat at the 2019 Mid-Winter Meeting. The Tool-Kit will be a web-based platform that will house all items related to theranostics, radioisotope therapy, etc. The Therapy Center and staff are working to compile a list of all the existing resources and will begin development of the site in the new year. Material from the Theranostics Conference in Las Vegas will be a great resource to add.

5. **Therapy Center Name Change**
   The SNMMI Board of Directors has asked the Therapy Center to discuss a name change would include the therapeutics that are not specific just to cancer. The Board agreed to keep the original name (Therapy Center of Excellence) but revise the mission statement to be more inclusive (see below). This proposal will be sent to the SNMMI Board of Directors during the meeting the end of September.

   **MISSION:**
   The **Therapy Center of Excellence** is an organizational component within the Society of Nuclear Medicine and Molecular Imaging, hereafter referred to as the Society or SNMMI, dedicated to all aspects of the development and utilization of therapy as an alternative to other treatments. The Center brings together constituents within this area creating a multi-disciplinary interest group whereby industry, 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 diagnostic and therapeutic radiopharmaceutical pairs in addition to therapies.

   - **The Therapy Center of Excellence:**
     - Provides a forum for members and non-members with similar interests
     - Provides expertise in nuclear oncology.
     - Fosters research and education in nuclear oncology and theranostics.
     - Provides outreach to other professionals and organizations
     - Nurtures new membership in SNMMI

6. **Internal Therapy Chair Task Force**
   This past year has been critical for SNMMI as we worked to initiate several new programs and partnerships within the therapy space. As there are multiple internal components within SNMMI working on therapy related activities, it was necessary to bring together the chairs/presidents of these groups to ensure no duplication of effort and collaboration whenever possible. The leadership of the Therapy Center of Excellence, Clinical Trials Network, Outreach Committee and Quality and Evidence Committee have participated in two conference calls in the past several months to discuss important strategies related to therapy. This group of expert leaders will continue to meet and strategize on SNMMI efforts within this area.

7. **Nuclear Medicine Global Initiative**
   The Nuclear Medicine Global Initiative (NMGI) agreed to move forward with Theranostics: an evidence-based NM value as the third topic. The new topic working group is being led by Jean-Luc Urbain, MD, PhD, CPE from Canada. The Therapy CoE has a representative on this group and will be working to provide the SNMMI perspective.
8. **Education**
   The Therapy CoE will submit proposals and organize sessions for the SNMMI Mid-Winter and Annual meetings in 2020.

   In addition, the Therapy CoE is also working with the Quality Committee on the Therapeutics Conference to be held in October in Las Vegas, NV.

9. **Newsletter**
   The Therapy Center will launch a newsletter to highlights its activities in support of promoting Therapy and to educate the SNMMI membership on developments in Theranostics.

10. **Intern**
    The Therapy CoE will support its intern with a substantial project as he completes his term by June 2019.

**Proposed FY20 Budget and Resource Requirements**

1. **Summary of Financial Needs**
   The Therapy CoE is requesting funds from the SNMMI to support travel for SNMMI members to the Multilateral Consensus Conference ($4000) and the Theranostics Consensus Conference ($16,000). The other FY19 goals of the Therapy Center will be supported by the attached budget.

2. **Resource Requirements**
   No additional staff, materials, technology, or marketing support is required beyond the usual support provided by SNMMI headquarters.
Therapy Center of Excellence
Background Overview

1. Mission
Therapy CoE is an organizational component within the SNMMI dedicated to all aspects of the development and utilization of Targeted Radioisotope Therapy (TRT) as an alternative to other treatments. Specifically, the new center will bring 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.

The Therapy Center of Excellence:
   (a) Provides a forum for members with similar interests
   (b) Provides expertise in TRT
   (c) Fosters research and education in TRT
   (d) Provides outreach to other professionals and organizations
   (e) Nurtures new membership in SNMMI

2. Therapy CoE Board of Directors

   Officers
   President: Dan Lee, MD  
   June 2019 – June 2021
   Vice President: Neeta Pandit-Taskar, MD  
   June 2019 – June 2021
   Secretary/Treasurer: Alan K. Klitzke, MD, FACM  
   June 2019 – June 2021
   Immediate Past President: Dan Pryma  
   June 2019 – June 2021

   Directors
   Richard Baum, MD, PhD  
   June 2017 – June 2020
   Heather Jacene, MD  
   June 2017 – June 2020
   Mathew L. Thakur, PhD  
   June 2017 – June 2020
   Satoshi Minoshima, MD, PhD  
   June 2017 – June 2020
   Anca M. Avram, MD, FACNM  
   June 2018 – June 2021
   Thomas A. Hope, MD  
   June 2018 – June 2021
   Rathan M. Subramaniam, MD, PhD, MPH, FACNM  
   June 2018 – June 2021
   *Suzanne E. Lapi, PhD  
   June 2019 – June 2021
   Michael S. Hofman, MBBS  
   June 2019 – June 2022
   AJB (Sandy) McEwan, MD, FSNMMI  
   June 2019 – June 2022
   Yusuf Menda, MD  
   June 2019 – June 2022

   Intern (non-voting)
   Ali Salavati, MD, MPH  
   June 2019 – June 2021

3. Current Status

   a. Financial
   As of April 1, 2019, the Therapy CoE has a projected FY19 revenue of $15,043. This includes $4,958 in member dues and $15,043 carryover from FY19. Projected FY19 expenses total $9,243. Revenue is generated through membership dues, which are $15 annually per member.

   b. Membership
   As of June 19, 2019, there were 365 members in the Therapy CoE of which 304 were physicians and scientists, and 55 technologists. The annual membership counts for the past three years are shown below:
c. **Member Benefits**

Member benefits include:
- Eligibility to vote in the Therapy COE Board of Directors elections
- Newsletter
- Sponsored educational symposia related to members’ interests
- Therapy CoE E-Community
- A $20.00 discount for Therapy CoE sponsored categorical session.

4. **Accomplishments for FY2019**

During the past year the Therapy Center of Excellence was active in educational activities and outreach to the broader medical community. The highlights of the Center’s activities are listed below:

a. **SNMMI 2019 Mid-Winter Meeting**

- Molecular and Genomic Theranostics in Thyroid Cancer: The Evolving Role for Nuclear Medicine—with GCNMC
- Theranostic Agents: What’s New and what’s on the Horizon—with CTN and PET COE
- Nuts & Bolts of Using PRRT—with PET COE and CTN

b. **Multilateral Conference**

Therapy Center's Committee on Radioiodine Therapy (CORT), chaired by Douglas Van Nostrand, MD and Mark Tulchinsky, MD led the SNMMI in driving forward the collaboration with and participating in the Multilateral Conference on Differentiated Thyroid Cancer held in Martinique in March 2019. Representatives of SNMMI, the European Association of Nuclear Medicine (EANM), the European Thyroid Association (ETA) and American Thyroid Association (ATA) discussed issues related to the care of patients with thyroid cancer, with focus on radioactive iodine (RAI) therapy.

Over two days of presentations, debate and discussion, moderated by Laszlo Hegedüs, MD, they addressed formalizing dialogue and activities among the four societies, indications and optimal prescribed activity for RAI adjuvant therapy, and definition and classification of radioiodine refractory thyroid cancer. The group synthesized the proceedings into what are being called the “Martinique Principles,” which consist of the major points that the attendees agreed upon and define terminology and outline areas of controversy and goals for future study.

Over the next few months, the group developed a white paper (“Controversies, Consensus and Collaboration in the Use of I-131 Therapy in Differentiated Thyroid Cancer: A Joint Statement from the American Thyroid Association, the European Association of Nuclear Medicine, the Society of Nuclear Medicine and Molecular Imaging and the European Thyroid Association”) which will be submitted to ATA’s journal, Thyroid, with possible editorials published in The Journal of Nuclear Medicine, European Journal of Nuclear Medicine, and European Thyroid Journal. Each organization is asked to endorse this white paper.

c. **Commentary on the Molenaar paper**

CORT and the Therapy Center board spearheaded SNMMI’s response to a paper in the Journal of Clinical Oncology, Risk of Hematologic Malignancies after Radioiodine Treatment of Well-Differentiated Thyroid Cancer” (J Clin Oncol. 2017 Dec 18: JCO2017750232. doi: 10.1200/JCO.2017.75.0232) which explored the risks of developing secondary hematological malignancies (SHM) in patients with well-differentiated thyroid cancers (WDTC) who receive radioactive iodine (RAI) after surgery. SNMMI was concerned that certain aspects of the
presentation of the data could result in changes in clinical practice which were unwarranted. SNMMI submitted a commentary to JCO. Therapy Center also supported an independent analysis of the data by a statistician to support individual commentary.

d. Training and Experience Requirements
The Training and Experience committee of the TCoE was tasked with reviewing Advisory Committee on Medical Use of Isotopes (ACMUI’s) CFR sub parts E 35.390. The committee developed recommended competencies to provide ACMUI on behalf of SNMMI.

e. ASTRO/SNMMI Task Force on Theranostics
Earlier this year, SNMMI partnered with American Society for Radiation Oncology (ASTRO) to form a joint task force. John Buatti, MD, Chair of the ASTRO Task Group on Theranostics, reached out to me regarding the formation of a collaborative working group with SNMMI to strategize on theranostics. The first conference call was held in March and the group agreed on the following next steps:
   1. Create a sub-group focused on developing the care pathway/workflow.
   2. Create a sub-group focused on training and education requirements.
   3. Contact AAPM to see if we can collaborate on their existing individual’s dosimetry task force. (It was suspected that both ASTRO and SNMMI already have individuals serving on the task force who are members of both organizations.)
   4. Organize a leadership meeting during the SNMMI Annual Meeting in June.
   5. Organize a 90-minute CE session at the SNMMI annual meeting on individual dosimetry.
   6. ASTRO is organizing a ½ day session at the ASTRO Annual meeting on theranostics.

Collaboration with ASTRO will assist SNMMI in defining optimal training and experience requirements beyond radiation sciences such as clinical competence in oncology as well as NRC regulations; and in developing guidelines on how and when to do dosimetry.

In addition, based on the discussions and conclusions of these two working groups, the Therapy Center will work to gain the formal board approval from both ASTRO and SNMMI and disseminate this important information to not only the nuclear medicine and molecular imaging community, but to all those involved in this area.

f. Educational Sessions at the 2019 SNMMI Annual Meeting
   - Thyroid Cancer Theranostics – The Evolving Role for Nuclear Medicine in Clinical Genomics Paradigm
   - Prostate Cancer Nuts and Bolts: Diagnosis and Therapy
   - Differentiated Thyroid Cancer Theranostics Practicum
   - Current Uses of MIBG and New Directions
   - Saul Hertz Award Symposium: The Atomic Cocktail of Radioiodine Ushers in Precision Oncology
   - The Era of PRRT: Personalization, Integrations and Future Perspectives

g. Saul Hertz Award
The 2019 awardee was Richard Baum, MD, PhD who gave a presentation entitled “The Atomic Cocktail of Radioiodine Ushers in Precision Oncology” during the symposium at the SNMMI Annual Meeting.

h. Young Investigator Awards
These awards are funded by the Education and Research Foundation for Nuclear Medicine and Molecular Imaging. The 2019 Therapy CoE YIA winners are:

   1st Place – Sanjana Ballal
"Early results of Ac-DOTATATE Targeted Alpha Therapy in Metastatic Gastroenteropancreatic Neuroendocrine Tumors: First Clinical Experience on Safety and Efficacy"

2nd Place – Andrei Gafita
"Predictive value of interim PSMA PET during Lu-PSMA radioligand therapy for overall survival in patients with advanced prostate cancer."

3rd Place – Frank Lin
"Effects of amino acid co-infusion on increased catecholamine symptoms in metastatic pheochromocytoma patients treated with 177Lu-DOTATATE"