SOCIETY OF NUCLEAR MEDICINE AND MOLECULAR IMAGING
CLINICAL TRIALS NETWORK

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THE CLINICAL TRIALS NETWORK NEWSLETTER

Pathways

Table of Contents

^{18}F Flurpiridaz Shows Promise as a Diagnostic Imaging Agent for CAD

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GE Healthcare and Lantheus Holdings, Inc. (NASDAQ: LNTH), parent company of Lantheus Medical Imaging, Inc. (collectively "Lantheus"), have begun a second Phase 3 clinical trial of ^{18}F-flurpiridaz injection PET myocardial perfusion imaging (the AURORA study; NCT03354273) for the detection of coronary artery disease (CAD), the most common form of heart disease. CAD affects an estimated 15.5 million Americans 20 years of age or older and is the leading cause of death in the United States and Europe.[1]

As per ASNC 2016 Guidelines, "rest-stress myocardial perfusion PET is recommended for patients with suspected active CAD, who meet appropriate criteria for a stress imaging test, and who also meet one or more of the following criteria:

1. prior stress imaging study that was of poor quality, equivocal or inconclusive
2. high-risk patients
3. those with body characteristics that commonly affect image quality including large breasts, breast implants, and obesity (BMI greater than 30)," as well as other characteristics.[2]

An ^{18}F-flurpiridaz injection is an ^{18}F-labeled novel investigational diagnostic tracer undergoing development for PET myocardial perfusion imaging (MPI) in those with suspected coronary artery disease. A total of 1,012 patients have been administered an ^{18}F-flurpiridaz injection over the course of three Phase 1, one Phase 2, and one Phase 3 studies. Results of the Phase 2 study have been reported elsewhere,[3] and results of the first Phase 3 study have been submitted for publication.

The AURORA study is an international multicenter study to evaluate diagnostic efficacy of ^{18}F-flurpiridaz injection PET MPI in the detection of CAD. In this prospective, open-label study, patients with suspected coronary artery disease, for whom an intracoronary angiography has been indicated, will undergo a SPECT MPI and ^{18}F-flurpiridaz injection PET MPI prior to the performance of coronary angiography. The primary endpoint is the diagnostic efficacy (sensitivity and specificity) of ^{18}F-flurpiridaz injection PET MPI for the detection of significant CAD, with the secondary endpoint being the diagnostic performance of ^{18}F-flurpiridaz injection PET MPI compared to SPECT. The study was officially launched on June 8, 2018, and is actively enrolling. A total of 650 patients will be enrolled in the study with the last patient enrollment—last patient follow-up projected to occur around August of 2020.

References

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2. American Society of Nuclear Cardiology and Society of Nuclear Medicine and Molecular Imaging Joint Position Statement on the Clinical Indications for Myocardial Perfusion PET. 2016. *J Nucl Cardiol* 23(5):1227-1231.
3. Berman, DS, Maddahi J, Tamarappoo BK, Czernin J, Taillefer R, et al. Flurpiridaz F 18 PET: Phase II Safety and Clinical Comparison with SPECT Myocardial Perfusion Imaging for Detection of Coronary Artery Disease. 2013. *J Am Coll Cardiol* 61(4): 469-477.

SPECIAL FEATURE

Theranostics Consensus Conference

John Sunderland, PhD, MBA, CTN Co-Chair
Jonathan McConathy, MD, PhD, CTN Co-Chair

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Jonathan E. McConathy, MD, PhD
Director, Advanced Imaging Facility and Director, Division of Molecular Imaging and Therapeutics, University of Alabama-Birmingham

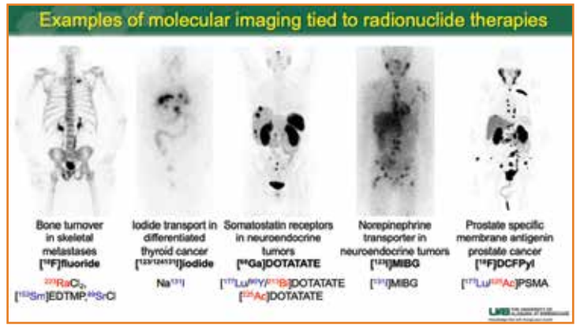
The Society of Nuclear Medicine and Molecular Imaging's Therapy Center of Excellence and the Clinical Trials Network co-sponsored a conference on November 8-9, 2018, hosted by the National Cancer Institute (NCI). This "Theranostics Consensus Conference 2018" was held at the Natcher Conference Center's Bethesda, Maryland, campus and sponsored by Progenics Pharmaceuticals. The goal of the two-day meeting was to gather representatives from major stakeholders in the theranostics space—including representatives from the Food and Drug Administration (FDA), NCI, academicians, clinical physicians, and pharmaceutical company executives—to develop guidelines for efficient clinical trial design targeting the collection of necessary data for both successful regulatory filings and timely and reasonable reimbursement of theranostic agents.

Theranostic agents and technologies are a relatively new class of products that combine highly targeted diagnostic imaging agents, typically radiolabeled with short-lived radionuclides, with nearly identical therapeutic molecules, radiolabeled with longer-lived particle-emitting radionuclides designed to effectively treat cancers. It is globally accepted by the medical community that theranostic agents and technologies are both efficient and successful in treating some cancers. Because these paired diagnostic and therapeutic agents are administered in very low-mass doses and treat through highly localized and biologically directed radiation effects (rather than pharmacologic action), they present challenges to the current regulatory and reimbursement paradigms that will substantially impact clinical trial design. Sharing perspective on these new agents from scientific, regulatory, societal, and reimbursement angles creates potential for prospective identification critical clinical trial data collection strategies that will speed the diagnostic and therapeutic development and commercialization process while ensuring the collection of most-appropriate safety and efficacy data. Figure 1 demonstrates examples pairing certain imaging agents with their theranostic counterpart.

The primary goal of the conference was two-fold:

1. Outline a pathway for the regulatory approval of targeted radiotherapies and their companion diagnostic.
2. Identify the data needed by government and private payers to support reimbursement for imaging and therapeutic agents.

Education sessions and Q&A panels focused on key elements within this evolving field of nuclear medicine, including the current state of theranostic technology and the challenges facing theranostic developers. With all stakeholders represented, participants had productive discussions on strategies to study two investigational agents (diagnostic and therapeutic) in a single trial; personalized dosimetry needs—balancing cost with outcome; and science and data required to support reimbursement of both agents—cost-effectiveness and outcomes. Day Two opened with a session on trial design, beginning with a discussion around PSMA molecules for prostate cancer.



Currently, studies target metastatic castrate-resistant patients who have failed a number of prior therapies. During this session the group discussed strategies to study these novel therapies in the context of clinical trials earlier on the disease process. Other panels discussed study endpoints beyond overall survival and progression-free survival as well as strategies to expand patient populations and label indications within the same mechanism of action for an approved drug. Finally, physicians representing SNMMI, the American Society for Radiation Oncology, and the American Board of Nuclear Medicine discussed the training needed to administer radiotherapeutics, and an additional presentation proposed a template for training requirements for theranostics physicists involved in clinical dosimetry calculations. FDA was highly engaged in discussions throughout, providing valuable perspectives and advice from a regulatory development standpoint. NCI was similarly active, providing perspective from both the Division of Cancer Treatment and from the Cancer Imaging Program; each provided valuable information on funding strategies ranging from Small Business Innovation Research (SBIR) grants to NCI's Experimental Therapeutics Program or NExT.

Key takeaways from the meeting include the need to determine what role, if any, personalized dosimetry should play in clinical trials and subsequent clinical practice. The bulk of the recent experience with radionuclide therapy has been in late-stage patients where long-term toxicity effects of radiation are not a concern. The field needs to determine when it is safe to administer these agents earlier in the disease course, when the patients may have longer life expectancy.

Continued on page 7. See **Theranostics Consensus Conference**

Radiotherapy SPOTLIGHT

Radiopharmaceuticals for Cardiac PET Imaging

David W. Dick, PhD; Chief of Radionuclide Production & PET Radiochemistry, University of Iowa

David W. Dick, PhD

The clinical value of cardiac positron emission tomography (PET) imaging with nitrogen-13 was demonstrated more than 20 years ago[1], but the requirement of a cyclotron within the imaging facility, radiopharmaceutical expense and the lack of reimbursement for clinical PET studies were barriers to its widespread use. Advances in medical imaging technology have led to an increased demand for radiopharmaceuticals that provide early and accurate diagnosis of cardiac function and disease states[2]. The latest advances in PET/CT equipment have reduced patient dose while improving imaging quality, and simultaneous assessment of both anatomy and perfusion by PET/CT can result in improved diagnostic accuracy. PET-myocardial perfusion imaging (MPI) allows accurate measurement of myocardial perfusion, absolute myocardial blood flow and function at stress and rest in a single study session performed in approximately 30 minutes[3]. Dynamic myocardial blood flow analysis has demonstrated additional prognostic value beyond relative perfusion imaging. Studies have shown that PET-MPI provides higher diagnostic accuracy than SPECT-MPI for detection of coronary artery disease, having a higher sensitivity and specificity as well as lower radiation dose during a shorter examination time period[3]. Despite this, some insurance companies will not cover the cost of the MPI study without an equivocal positive or negative finding from other diagnostic methods.

Various PET tracers are available for MPI, with rubidium-82 chloride or nitrogen-13 ammonia most commonly used. Table 1 lists the half-lives of some PET radioisotopes used in cardiac imaging[2]. The half-life of these cardiac imaging agents and their sensitivity to specific disease states determines their use in cardiac PET protocols. The known tracer kinetics of PET radiopharmaceuticals, along with the advantages of PET (e.g., attenuation correction, high temporal resolution), allow absolute quantitation of myocardial blood flow. This provides an improved diagnosis of coronary artery disease.[1] Access to these agents is still a factor for some facilities, although the development of radionuclide generators replaces the need of a cyclotron in some cases. The main disadvantage of the available tracers is cost[1], and the community continues to work with Centers for Medicare and Medicaid Services (CMS) and insurance companies for reimbursement.

Table 1

Radioisotope	Half-life (minutes)
^{18}Fluorine	109.8
^{64}Copper	762
^{11}Carbon	20
^{68}Gallium	68
^{82}Rubidium	1.27
^{15}Oxygen	2.06
^{13}Nitrogen	9.97

PET Cardiac Protocols

Rest and Stress Imaging

- Rubidium 82(^{82}Rb): 40 mCi of ^{82}Rb is injected for a rest scan. During the stress test, administer lexiscan, then inject 40 mCi of ^{82}Rb.
- ^{13}N-Ammonia: inject 20 mCi for the rest scan. Since there is no generator involved (as with ^{82}Rb) and it's a syringe injection, the patient can be stressed using a treadmill or Lexiscan. If the patient is stressed using a treadmill the patient is injected with 20 mci of ^{13}N-Ammonia at peak heart rate and is then taken back to the PET/CT scanner for the stress scan. If the patient is stressed by a pharmacological agent the patient is in the PET/CT scanner and is injected with lexiscan followed by 20 mci of ^{13}N-Ammonia with imaging to follow.

Rest and Myocardial Viability

- Rubidium 82(^{82}Rb): inject 40 mCi of ^{82}Rb for the rest scan. After the ^{82}Rb rest test is complete, evaluate blood sugar and treat if necessary with dextrose or insulin. When ready, the patient can be injected with FDG to access myocardial viability. Inject 8-10 mCi of FDG and start scan one hour after injection.

The SNMMI 2018 Highlights Lecture, delivered June 26 at the SNMMI Annual Meeting in Philadelphia, was presented by Mehran M. Sadeghi, MD, a professor in the Department of Internal Medicine (Cardiology) at Yale University School of Medicine (New Haven, CT). He spoke on highlights in cardiovascular nuclear and molecular imaging and discussed some key works selected from the accepted group of 60 oral presentations and 65 posters. At the conclusion of his presentation[4], Dr. Sadeghi stated: "Our field is thriving with many refinements to perfusion imaging, new applications, and new tracers. Some of the new applications introduced in previous years are now fully integrated into clinical practice. Several innovations in the pipeline are expected to expand the utilization and value of nuclear and molecular imaging in cardiology."

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2. Davidson CQ, Phenix CP, Tai TC, Khaper N, and Lees SL. Searching for novel PET radiotracers: imaging cardiac perfusion, metabolism and inflammation. *Am J Nucl Med Mol Imaging* 2018;8(3):200-227.
3. Nakazato R, Berman DS, Alexanderson E, and Slomka P. Myocardial perfusion imaging with PET. *Imaging Med.* 2013 February 1; 5(1): 35–46.
4. 2018 SNMMI Highlights Lecture: Cardiovascular Nuclear and Molecular Imaging. Mehran M. Sadeghi, MD. *The Journal of Nuclear Medicine* (2018;59[suppl 1]).

CTN Highlights

CTN is once again partnering with other SNMMI centers and councils to offer valuable information to assist you in your practice. In addition to the general nuclear medicine sessions, a special track on cardiovascular imaging discusses current practices, presents interesting and puzzling cases, and explores what's on the horizon. CTN is sponsoring the two sessions listed below as part of the General Nuclear Medicine track.

Friday, January 18

- 8:00-10:00 am: Theranostics Agents Beyond Lutathera: What's New and What's on the Horizon
- 10:15 am-12:15 pm: Nuts and Bolts of Using PRRT

CTN 2019 Summer Webinar Series

The 2019 webinar series is focused on a review of radiopharmaceuticals used in imaging. This includes, in some cases, both PET and SPECT imaging. In addition to the topics provided below, one webinar will be dedicated to radiotherapies and new agents on the horizon.

Disciplines:

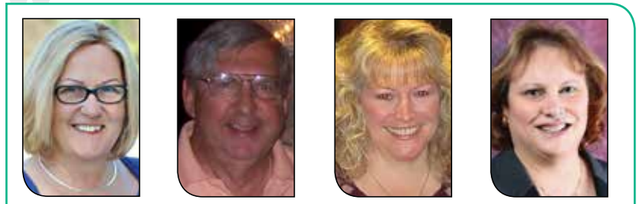
- Bone
- Infection
- Neurology
- Nuclear Cardiology
- Oncology
- Pediatrics

CTN will update the webinar information as speakers and dates are confirmed. Please check the CTN website in 2019 for the final schedule.

Tech Talk

Monitoring Essentials of Clinical Trials Involving Radiopharmaceuticals

Ing-Mari Bahr, CNMT, President;
Robert Dann, Sr. CRA;
Lisa Hall, RT(R) MR, Sr. CRA;
Terri Clark, VP Global Clinical Operations
Trial Care International, LLC


Ing-Mari Bahr, CNMT | Robert Dann, Sr. CRA | Lisa Hall, RT(R) MR, Sr. CRA | Terri Clark

All clinical trials are highly regulated and are usually monitored onsite by experienced clinical research associates (CRAs). What we have found, after years of being involved in clinical trials, is that the experience of the CRA is of most importance when the trial involves a radiopharmaceutical, either as the investigational agent, such as a new cancer imaging agent or therapeutic, or as a measure of the clinical endpoint, such as an FDG PET scan. Only a small percentage of CRAs are qualified and prepared to provide the additional level of review imposed by the nature of radiopharmaceuticals. A trained nuclear medicine/radiology technologist, with the appropriate experience, may want to consider becoming a CRA.

As a clinical research organization (CRO) specializing in imaging/radiotherapeutics/theranostics, with more than 100 years in the field combined, we present a brief overview of areas identified as important when monitoring a clinical trial with imaging components.

Site Identification: In the process of selecting a site for this type of trial, it is essential for the CRA to

- understand the path of adding a new isotope to the current RAM license;
- evaluate imaging equipment and software to be used;
- confirm proper quality control (QC) evaluation of images before site selection and ongoing throughout study;
- evaluate appropriate location for IP reconstitution and administration such as lead-lined walls, etc.;
- evaluate appropriate location for subject isolation post-administration; and
- ensure access to any and all correlative imaging modalities and coordination with other departments.

During the Study: The CRA performs a number of vital tasks directly related to imaging that include

- image evaluation to ensure quality, correct anatomy imaged, processing, and imaging protocol compliance, and feedback on quality and technique;
- training onsite readers and technologists;
- providing onsite imaging support for the first few subjects imaged;
- providing technologist support off-site;
- ensuring proper deidentification of data and image submission;
- addressing any radiobiology questions including implications for staff, subjects, and families; and
- ensuring ongoing QC of imaging devices and dose calibrators.

Radiation-related Procedures: The CRA develops the radio-pharmacy manual and

- provides training of the staff on dosing to include IP preparation, reconstitution, and administration;
- ensures appropriate technique and proper accountability and documentation;
- reviews decay correction and dosing rules and proposes radiation dosimetry-based adjustments; and
- reviews correlative studies such as other nuclear medicine and CT scans to ensure overall radiation burden is not exceeding predefined limits.

Additionally, the CRA also may need to provide guidance and training for the imaging core lab used to establish flow of documents and images, develop the core lab charter and imaging manual, set up blinded reads and select and train blinded readers, and ensure proper conduct of blinded reads.

With the increase of new products using PET imaging to determine imaging endpoints and the development of new radiotherapeutics, a CRA with imaging expertise is of essential value in the execution of a successful clinical trial. If the above skillset aligns with your experience and sounds interesting, becoming a CRA could be a great potential career path for you.

Tech Tip

Avoiding Common Artifacts in Cardiac PET Imaging

Tessa Ocampo Johnson, MBA, CNMT

Artifacts can occur in cardiac PET imaging, and I dealt with many of them throughout my years as a clinical Nuclear Medicine Technologist. The most commonly seen are metal artifacts and anatomical misalignment due to patient motion. Motion artifacts can cause an artifactual abnormality resulting in a false positive defect on a cardiac PET images. Here are some tips to avoid these artifacts.

Metal Artifacts: Remove all metal around the neck

- Out-patient: It is best to put the patient in a gown - I've found lucky coins and prayer pins on the inside of patient's shirts that became detectable in the CT attenuation correction scan. I have also learned you can never assume when a patient says their shirt has plastic embellishments. The plastic embellishments are usually made of metal.
- In-patient: An in-patient may have a medicine pump or a heart monitor device that is located in the chest area. While you cannot remove these, it is best to relocate the medical device to either above or below the heart so it will not mask the heart during the scan.

Patient Motion: Encourage relaxation

- Improve patient comfort: Misalignments from motion during a scan causes a misinterpretation due to degrading imaging quality. Do everything you can to make the patient comfortable before the scan - an extra pillow, a warm blanket, and a cushion underneath their elbows are examples of methods I have used with success.
- Communication: Talk to the patient and explain what will happen. Discuss the instructions for scanning with the patient that may involve a breath hold during the CT attenuation scan so as to reduce misalignment during the PET scan. Also inform the patient of all the side effects that may occur during the pharmacological stress test and urge your patient to remain calm and to communicate with the technologist or nurse if he or she is having a side effect. If the patient feels nervous or is scared, there may be movement during the scan.

Various types of artifacts may occur due to other factors, but these are the most common and the easiest to avoid. While we cannot avoid an implanted metal devices located near the heart a technologist can avoid external metals and some patient motion.

References:

1. Loghin C, Sdringola S, Gould L. Common Artifacts in PET Myocardial Perfusion Images Due to Attenuation-Emission Misregistration: Clinical Significance, Causes, and Solutions. *J. Nucl Med* 2004;45(6):1029-1039.
2. Vleeming EJ, Lazarenko SV, van der Zant FM, Pan XB, Declerck JM, et al. Cardiac Displacement During 13N-Ammonia Myocardial Perfusion PET/CT: Comparison Between Adenosine- and Regadenoson-Induced Stress. *J. Nucl Med Technol* 2018888; 46:111-122 doi:10.2967/jnmt.117.199463.

WHAT'S HAPPENING

CTN Internship Program

Internship can be an integral part of the education process in attaining a successful and satisfying career, especially when one is pursuing a pathway in a specialized field. As a Clinical Trials Network (CTN) intern, you are exposed to the multiple components related to clinical research and are expected to participate in projects involved in translating research into the clinic. By helping disparate groups from industry and academia to pool their efforts to moving novel radiopharmaceuticals into the clinical space, you are participating in a rapidly expanding field of theranostics and specialized imaging.

CTN comprises strong leadership and members—physicians, technologists, physicists, radiochemists, and industry—having many years of diverse experience in the field. Through greater standardization of imaging in clinical trials and facilitating the use of novel radiopharmaceuticals to into research projects, CTN directly helps promote the approval of new radiopharmaceuticals and educate users on the use of these tracers. This is a two-year mentorship for those interested in radiopharmaceutical development, clinical translation of approved radiotracers, and image standardization.

The application process is closed for this year, but read about our Internship program at SNMMI CTN Internship Program and click on **Internship**. If you have questions about the program, please contact CTN at ctnadmin@snmmi.org.

In the NEWS

AUC for PET Myocardial Perfusion Imaging

Sukhjeet Ahuja, MD, MPH, Director, Evidence and Quality Department, SNMMI

Sukhjeet Ahuja, MD, MPH

The 2014 Protecting Access to Medicare Act (PAMA)[1] established a new program under fee-for-service Medicare to promote the use of Appropriate Use Criteria (AUC) for Advanced Diagnostic Imaging Services (ADIS). This covers CT, MRI, and all Nuclear Medicine procedures including PET. PAMA requires referring physicians to consult AUC developed by a Centers for Medicare and Medicaid Services (CMS)-approved Provider Led Entity or "PLE" (usually a specialty society such as SNMMI) to ensure cost-effectiveness and appropriate utilization of ADIS. Under the program, AUC may be developed only by organizations that are deemed to be "qualified provider-led entities (Q-PLE)" by the CMS. After going through a rigorous and extensive application, SNMMI was approved as a Q-PLE in June 2016.

SNMMI modeled its AUC development process after the RAND/UCLA Appropriateness Method,[2] including a systematic review of evidence followed by development of AUC for various common clinical scenarios using a modified Delphi[3] approach. This process is also consistent with the Institute of Medicine's standards for developing trustworthy clinical guidance documents. To conduct independent and objective systematic reviews of the literature, SNMMI has contracted with the Oregon Health and Science University's Evidence-based Practice Center. The primary purpose of these systematic reviews is to assess the literature for evidence describing the diagnostic accuracy and comparative effectiveness of selected Nuclear Medicine procedures in clinical decision making and patient outcomes.

One of the high-value topics on which AUC are currently under development is PET Myocardial Perfusion Imaging. This endeavor is being led by Thomas H. Schindler, MD, PhD, with Washington University of St. Louis. It is a true multidisciplinary effort with official representation from several relevant specialty societies. In addition to the representatives from SNMMI, the expert panel for this AUC workgroup includes nominees from the American College of Cardiology, the American Society of Nuclear Cardiology, the Canadian Cardiovascular Society, the European Association of Nuclear Medicine, the American College of Nuclear Medicine, and the American College of Physicians. The expert panel has identified more than 260 clinical scenarios for PET MPI and is currently in the process of finalizing the appropriateness scores for these indications. The anticipated completion for this AUC is the first quarter of 2019. More information on the society's AUC related efforts can be found at www.snmmi.org/AUC.

References:

1. PAMA: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-regulations.html.
2. Fitch K, Bernstein SJ, Aguilar MD, Aguilar MS, Burnand B, Ramón J, et al. *The RAND/UCLA Appropriateness Method User's Manual*. Santa Monica, CA: Rand, 2001.
3. Delphi method: https://www.investopedia.com/terms/d/delphi-method.asp.

Theranostics Consensus Conference Continued from page 2.

The clinical trials for this early stage will require the identification of new study endpoints—perhaps an imaging endpoint. Lastly, as a field, we must ensure that we have the workforce that is adequately trained in the use of radionuclide therapies.

A summary paper will be published, and sessions from the conference were recorded and will be made available for members to view online. This important discussion will continue during a categorical at the SNMMI 2019 Annual Meeting in Anaheim, CA (June 22-25).

We would like to recognize Daniel Pryma, MD (president of the SNMMI Therapy Center of Excellence), Daniel Lee, MD (vice president of the SNMMI Therapy Center of Excellence), and John Sunderland, PhD, MBA (Clinical Trials Network co-chair), as the organizers of this initial consensus conference. Additionally, we wish to thank FDA and NCI for their commitment and dedication to the conference; their participation in formal talks and hallway conversations were valued by the attendees. Thank you for your hard work in leading this cutting-edge space of research and medicine!

The slides from the conference will soon be available on the CTN website: **www.snmmi.org/ctn**

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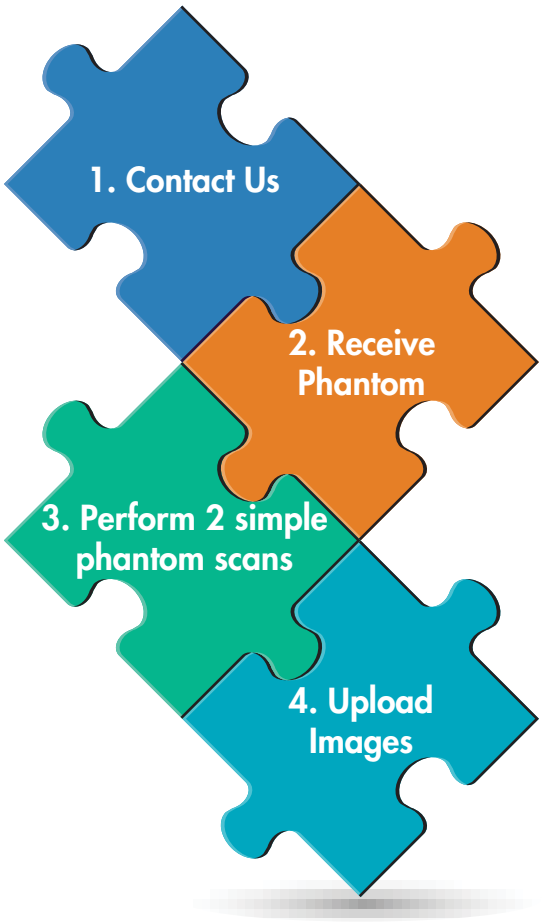

Save the Dates

SNMMI 2019 Mid-Winter Meeting
January 17–19, 2019 • Palm Springs, CA

5th Theranostics World Congress 2019
March 1–3, 2019 • Jeju-do, Korea

40th Annual High-Country Nuclear Medicine Conference
March 2–6, 2019 • Vail, CO

ASNC Nuclear Cardiology Today 2019
April 12–14, 2019 • Tampa, FL

ASCO Annual Meeting 2019
May 31–June 4, 2019 • Chicago, IL

SNMMI 2019 Annual Meeting
June 22–25, 2019 • Anaheim, CA

DIA Annual Meeting 2019
June 23–27, 2019 • San Diego, CA

WMIC 2019—World Molecular Imaging Congress
September 4–7, 2019 • Montreal, Quebec

European Association of Nuclear Medicine (EANM19)
October 12–16, 2019 • Barcelona, Spain

RSNA 105th Scientific Assembly and Annual Meeting
December 1–5, 2019 • Chicago, IL

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