SOCIETY OF NUCLEAR MEDICINE AND MOLECULAR IMAGING
CLINICAL TRIALS NETWORK

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THE CLINICAL TRIALS NETWORK NEWSLETTER

Pathways

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^{68}Ga PET/CT Advances in the United States: A Personal Journey

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President, NorCal CarciNET
Community Chair, SNMMI
Patient Advocacy Advisory Board

When you are diagnosed with a rare disease, you struggle to get information, worry that not enough resources are being dedicated to its management and search for any information to better understand all aspects of the disease. This quest often leads to an unexpected journey, as it did for me when I was diagnosed in 2007 with an inoperable neuroendocrine tumor (NET) of the pancreas (incidence of 1 in 1,000,000), and I vowed to learn all I could about this disease.

Initially seen at the University of California, San Francisco (UCSF), my local care team was excellent, but there was little they could do other than watchful waiting. To better educate myself during this time, I attended the International Patient Conference in Toronto in October of 2008 where Richard Baum, MD, PhD, (Bad Berka, Germany) gave an intriguing lecture on a new approach to imaging NETs using an agent not available in the United States. He reported that when a radiotracer called "Gallium-68" (^{68}Ga) was used with PET/CT imaging, one out of three patients scanned showed either spread of the disease into organs not previously involved or discovered unknown primaries. With Dr. Baum's permission, I went to Germany and had one of these scans performed. Little did I know then where this path would lead.

Results of my first ^{68}Ga PET/CT matched my initial Octreoscan™, showing stable disease on the pancreas and liver. While my clinical outcome had not changed, I was impressed that a full body scan could be administered and completed in less than four hours as opposed to two days for the Octreoscan. My scan also indicated that I would be a good candidate for peptide receptor radionuclide therapy (PRRT). Six months later, my disease progressed, and I was back in Germany for the first of three rounds of PRRT and follow-up ^{68}Ga PET/CT scans. Using my experience, and with input from Dr. Baum and another patient, I created PRRTInfo.org to help others adrift in the same boat.

At Dr. Baum's invitation, I attended the 1st World Congress of ^{68}Ga and PRRT in Bad Berka in 2011. Nearly 450 medical professionals—and four patients—from around the world attended. At this meeting, I was fortunate to spend time with Eric Liu, MD, whose team at Vanderbilt University would be the first to submit an investigational new drug (IND) application for ^{68}Ga DOTATATE, and Tom O'Dorisio, MD, whose team at the

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^{68}Ga PET/CT Continued from page 1.

University of Iowa would get approval for the second IND—this one for ^{68}Ga DOTATOC. It was also during one of the Congress' receptions that I met Henry VanBrocklin, PhD, who was, coincidentally, on staff at UCSF and lived only 10 miles from my house. As co-chair of the SNMMI Outreach Committee, he asked me to join their Patient Advocacy Advisory Board. Our similar goals brought us together and then took me on a new course.

In January 2012, I was invited to attend a ^{68}Ga Users Group meeting during the SNMMI Mid-Winter Meeting in Orlando, Fla. At this meeting, there was intense discussion about which peptide—DOTATOC or DOTATATE—the group would support going forward. This debate seemed to stall the process initially, but a smaller working group was formed to sift through the data and make recommendations to the larger Users Group. Shortly after this meeting, I was asked to participate in the working group to provide input from a different viewpoint—as a patient advocate. At the SNMMI 2012 Annual Meeting in Miami, Fla., CTN became involved and charged with spearheading the group's efforts to move a peptide to approval. The decision to go forward with only one peptide morphed into support for a generic DOTA-XXX protocol that harmonized the work done to date at major academic centers and would streamline efforts to submit a future FDA New Drug Application (NDA) for ^{68}Ga.

The working group meetings and calls during the past year have focused on getting meaningful information out to the research community and harmonizing a ^{68}Ga IND template for qualified sites to use. At the SNMMI 2013 Annual Meeting in Vancouver, British Columbia, Canada, the working group hosted an hour-long "open" session to present progress to date, including our work on the IND protocol and forms, the current patent status on DOTA-XXX and information on cost recovery for ^{68}Ga PET scans. It was also decided that DOTATOC would be the first peptide to submit to the FDA for Orphan Drug Designation.

As outreach to fellow medical professionals is critical to expand the use of ^{68}Ga in the clinic, the group presented a poster on its progress at the October 2013 North American Neuroendocrine Tumor Society's (NANETS) annual meeting in Charleston, SC. Although oncologists acknowledged the beauty of ^{68}Ga images, many are still unconvinced that this agent would be of value in their practice or affect changes to treatment decisions. Education, like this poster, and presentations at meetings, are needed to help change that perception.

Friends and other patients often ask why I travel outside the United States for imaging and treatment. There are often very limited resources available to the patient with a rare disease, and these diseases rarely garner much interest in the drug development market as interests wane when financial gain is little to none. It was heartening to see that efforts were now moving forward to bringing ^{68}Ga scans to patients in the United States.

As a patient of a rare disease, I was and continue to be impressed with the ^{68}Ga Users Group's passion and ongoing volunteer efforts to make this agent more available to investigators and their patients. Through education, exploration and enduring relationships, I am now an active member of the ^{68}Ga Users Group and chair of the SNMMI's Patient Advocacy Advisory Board. Both I and the NET patient community thank members of the ^{68}Ga Users Group, CTN and SNMMI for the time and resources devoted to ^{68}Ga PET/CT for NETs in the United States. While the path has not always been smooth or straight, those working on the project have never wavered in their desire to help the patient community.

Message from the Co-Chairs:
CTN Forms SPECT Committee

In 2008, when SNMMI established CTN, it outlined a number of areas where CTN could make an impact in the community. One of the goals outlined in its three-year strategic plan was to "facilitate access to investigational molecular imaging biomarkers, including positron emission tomography/computed tomography (PET/CT) and single photon emission computed tomography (SPECT) agents." Since a considerable amount of this early span of time was spent addressing the pressing need to help bring PET/CT agents into the clinical research setting and to help gain approval for clinical practice, efforts to support SPECT agents took a backseat—until recently. CTN, with support of the SNMMI leadership, has created the SPECT Committee to work with other CTN and SNMMI committees—and the community as a whole—to start closing the research gaps in this area.

Chaired by Jonathon Nye, PhD, of Emory University, the committee is comprised of imaging physicists and physicians who plan to focus their efforts on developing SPECT imaging manuals and reviewing imaging components and endpoints in clinical trial design using novel SPECT agents; creating a list of contract physicists who can perform on-site validation of SPECT cameras (with or without CT) for clinical trials; educating study site imaging staff on SPECT protocol and general research and design; and developing a new SPECT phantom with optimal settings for research imaging validations. The committee's first meeting takes place during the SNMMI 2014 Mid-Winter Meeting in Palm Springs, Calif.

Clinical Trials Network Co-Chairs

Michael Graham, PhD, MD

John Hoffman, MD

In the NEWS

NMCTG Hired to Coordinate Movember Studies

The SNMMI Nuclear Medicine Clinical Trial Group, LLC (NMCTG) was awarded funding by the Movember Foundation in Australia to manage key projects recently funded under their Global Action Plan 2 initiative on developing novel radiopharmaceuticals for imaging prostate cancer. The key goal of this project is to help standardize the imaging obtained on subjects at over 15 academic institutions around the world. Using the FDA-approved Keosys Imagys® clinical trials imaging workstation already set up in the SNMMI home office (Reston, Va), participating study sites upload imaging and clinical data that can then be downloaded, reviewed and analyzed by Movember and the trial site investigators. The NMCTG is not performing any image interpretation for the trials; sites perform their own reads and interpretations for their individual studies.

This is going to be an important, exciting and fast-paced endeavor. Study preparations are underway, and first patients are anticipated to be recruited first quarter 2014.

^{68}Ga-DOTATOC Receives FDA Orphan Drug Designation

On August 12, 2013, CTN submitted an application to the U.S. Food and Drug Administration (FDA) for orphan drug designation for Gallium-68 (DOTA0-Phel-Tyr3)octreotid (^{68}Ga-DOTATOC). The Orphan Drug Act (ODA) provides for granting special status to a drug or biological product ("drug") to treat a rare disease or condition. For a drug to qualify for orphan designation both the drug and the disease or condition must meet certain criteria specified in the ODA and FDA's implementing regulations at 21 CFR Part 316. One of two requirements must be met. Either the number of people affected by the disease or condition for which the drug is to be developed is fewer than 200,000 persons, or there is no reasonable expectation that the sales of the drug will be sufficient to offset the costs of developing the drug for the U.S. market and making it available in the United States. The prevalence of NETs in the United States was reported to be 35/100,000 in 2008 (Yao et al, 2008). Although to population has increased, the prevalence is still well below 200,000.

On October 29, the FDA granted orphan drug status for the use of ^{68}Ga-DOTATOC for the management of neuroendocrine tumors. The announcement has garnered widespread interest and elevated enthusiasm for gallium imaging agents. CTN has talked with a number of groups at academic and government institutions, as well as industry in the United States and abroad, to help facilitate its expanded use in the clinic to manage neuroendocrine tumors. CTN has also developed harmonized release criteria for all DOTA agents and templates for an imaging manual, case report forms, and an informed consent. These documents are made available to qualified academic institutions to assist them in starting ^{68}Ga-DOTA trials. SNMMI and CTN are happy to be meeting their goal of expanding the use of ^{68}Ga-labeled imaging agents.

SNMMI 2014 Mid-Winter Meeting: CTN Preview

Joint CTN/CMIIT Symposium: Thursday, February 6

CTN is excited to co-sponsor a full-day symposium with the SNMMI Center for Molecular Imaging Innovation and Translation (CMIIT). Leaders in oncology, imaging and industry will present timely and important talks on "Molecular Imaging of Response to Therapy." Participants will hear about the different response measurement criteria methods, novel molecular imaging radiopharmaceuticals available for use in clinical oncology trials and what situations would best benefit from their use, and the challenges within the pharmaceutical industry to incorporate molecular imaging in oncologic trial design. The categorical is from 9 a.m. – 5 p.m. We hope you can attend.

Unique Session for Technologist Section: Saturday, February 8

Continuing CTN's collaboration with SNMMI's Technologist Section, a very unique session, "Opportunities for the Tech: Getting Your Foot in the Door," will be presented at the Mid-Winter Meeting. This course will review how to search the market for that ideal job, what to do when you identify it and how to be successful in obtaining it. This is a must-attend session if you are considering applying your nuclear medicine technology skills to a different career. Don't miss the half-day meeting on Saturday, February 8, from 8 a.m. – 12 p.m.

What's **Happening**

New Chair of CTN Site Education Committee Identified

We are pleased to announce that LisaAnn Trembath, CNMT, MSM, CCRA, has agreed to serve as chair of the busy CTN Site Education Committee. Trembath has more than 18 years of experience with sponsored clinical trials as a research technologist, study coordinator, clinical research monitor and project manager in both the academic medical center setting and pharmaceutical industry. She served as chair of this committee from 2008 until January 2012 and was instrumental in developing the foundation of the CTN educational program.

Assisting Trembath in an advisory role is Jeffrey Yap, PhD, whose activities within CTN include interim chair of this committee, chair of the Trial Design Committee and advisor to the Scanner Validation Program. We thank Marybeth Devine, BSRT(R)(N), CNMT, the past committee chair, for her hard work and commitment to excellence during her tenure and wish her the very best. She remains on the committee to help with future activities. We look forward to continued success under Trembath's guidance.

CTN Condensed Core Course Launched

The much-awaited CTN course, "Imaging in Clinical Research: Elements for Success," has been recorded and is available online in the SNMMI Learning Center. This comprehensive summary of the five CTN Core Courses on successfully performing imaging in clinical trials is presented in one 90-minute overview. The course offers continuing education credit and provides guidance for all study personnel—from imagers to site coordinators to investigators—in the following key areas:

- Identifying and defining common research terms used in clinical trials
- Describing procedures for documenting source data in a research study
- Explaining the importance of following the study-specific protocol and the imaging manual
- Distinguishing AEs from SAEs and being aware of when and how to report them
- Outlining the responsibilities associated with GCP, 21CFR312 and Form FDA1572

View all CTN educational offerings on our Education Program webpage.

New Version of CTN Database Launched

CTN is excited to announce its newly-designed and enhanced database of registered imaging sites and radiopharmaceutical manufacturers. This comprehensive, online compilation of research data is available to CTN industry partners for use in selecting sites and imaging agents for their studies. Additionally, data on scanner validations, cyclotrons and clinical trials performed with CTN services are collected. Sites will see a streamlined application to easily add their information and update it as needed. Manufacturing sites have a more detailed group of screens to select radiopharmaceuticals, radionuclides and precursors, as well as to provide information on the regulatory status of their products. Also new is a field requested by the National Institutes of Health to allow for collaboration and sharing of radiopharmaceutical investigational new drugs. The Database Reporting Tool (DaRT) feature remains an integral part of this database and is being updated to include all new fields. These upgrades give CTN even more resources to facilitate the use of imaging agents in clinical trials.

If your site has not yet joined CTN and would like your information included, please go to the CTN Database website (www.ctndatabase.org) and complete the information on the main screen.

CTN Numbers At-a-Glance

226 Validated PET/CT Scanners

157 Sites with Validated PET/CT Scanners

31 Fully Qualified Sites

24 Countries Represented in the Database

360 Registered Sites in the Database

BIOMARKER **SPOTLIGHT**

IMAGING WITH ^{99M}TC CONTINUES TO GAIN INTEREST DESPITE DISRUPTIONS IN AVAILABILITY

Jonathon A. Nye, PhD

The imaging of vascular perfusion with Tc-99m-labeled macroaggregated albumin (^{99m}Tc-MAA) has been available since the early 1970s.[1] The MAA particles (~10µm in diameter and greater) are introduced intravenously into the bloodstream and largely trapped in a single pass of the first capillary tree. For the purposes of quantifying lung perfusion or pulmonary embolism, greater than 80 percent[2] are trapped in the lungs within the first few minutes post intravenous injection. Subsequent A/P planar projections can then provide information on blood flow abnormalities. The increased availability of single photon emission computed tomography (SPECT) for vascular perfusion imaging has shown improvements in diagnostic certainty compared to planar projections due to its physical aspects such as better contrast visibility and assessment of defect size.[3] In regards to the diagnostic decision process, imaging of suspected pulmonary embolism with ^{99m}Tc-MAA is the preferred first choice method over helical computed tomography (CT) or CT angiography (CTA),[4,5] though they are largely considered equivalent.[6] Of particular concern with CT is the higher radiation dose to the breast when compared to ^{99m}Tc-MAA, which may warrant a change in clinical routine.[7]

In addition to lung perfusion imaging, off-label use of ^{99m}Tc-MAA provides valuable information on liver capillary perfusion and is employed in the treatment of radioembolization with ^{90}Y-labeled microspheres. Calculation of the liver-to-lung shunt fraction from A/P planar images of intra-arterial infused ^{99m}Tc-MAA (Figure 1) is a prerequisite for treatment planning decisions.[8] Although in many cases ^{99m}Tc-MAA imaging predicts the post-injection distribution of ^{90}Y activity on SPECT (Figure 2), these results are not always typical, and there is disagreement regarding the use of ^{99m}Tc-MAA for calculation of the imparted dose.[9,10] However, the safe and effective application of ^{99m}Tc-MAA in liver perfusion plays a large role in the workup of ^{90}Y radioembolization, including estimation of tumor-to-normal liver ratio and delineation of treatment volumes.

The availability of ^{99m}Tc-MAA has waned over the past several years due to a loss of manufacturers. The sole North American supplier of MAA kits, Jubilant DraxImage Inc. (JDI) experienced a shortage in MAA production due to changes in its manufacturing process in September of 2013. However, in mid-October 2013, DRAXIMAGE® MAA was been removed from the U.S. Food and Drug administration Current Drug Shortages Index and was manufactured on an accelerated schedule until an adequate supply was in stock.[12]

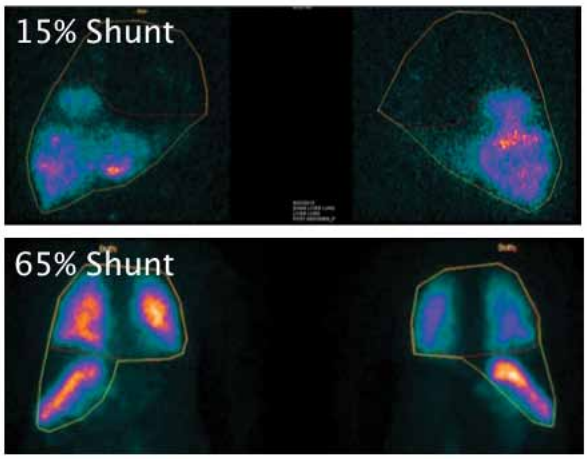

Figure 1. Liver-to-lung shunt quantitation with ^{99m}Tc-MAA imaging. In the case of the 65 percent shunt fraction, no treatment was administered. Images courtesy of James Galt, PhD, Emory University.

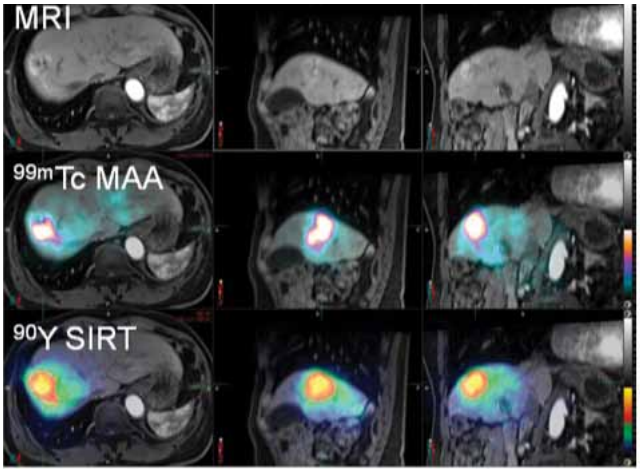

Figure 2. Registered and fused images of MRI, ^{99m}Tc-MAA SPECT/CT and ^{90}Y SIR-spheres SPECT/CT. Note the excellent correlation between the ^{99m}Tc-MAA staging image and ^{90}Y bremstrahlung post-treatment image. Images are courtesy of James Galt, PhD, Emory University.

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2. Malone, L.A., J.F. Malone, and J.T. Ennis, Kinetics of technetium 99m labelled macroaggregated albumin in humans. Br J Radiol, 1983. 56(662): p. 109-12.
3. Parker, J.A., Improving Lung Scintigraphy. Journal of Nuclear Medicine, 2009. 50(12): p. 1919-1920.

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Tech **Talk**

ADVENTURES OF A NEURO-PET TECH

Elizabeth Hackett, RT(N)(CT), PET

Working in the field of nuclear medicine is exciting as it is always evolving. I have been in this field for over 15 years, spending the last 12 years working in the Division of Translational Imaging at Columbia University/New York State Psychiatric Institute. The division specializes in the development of novel tools and techniques to study neurotransmission in the brain and the application of these techniques into clinical studies where we look at the chemical imbalances associated with severe mental illnesses and drug addiction using modalities such as positron emission tomography (PET) and magnetic resonance imaging.

When I joined this division, I was hired to only run the PET scanner. Since then, I have been promoted to management with increased responsibilities that include supervising research assistants, working alongside fellows and physicians, ensuring compliance with the institutional review board and the U.S. Food and Drug Administration for our protocols, and overseeing all aspects of clinical trials in our division. One of the ways I was able to do this was by building upon my nuclear medicine technology degree, completing additional imaging education, such as in computed tomography, and also by earning a business degree. I am the type of person who always wants to learn, know what is going on and see how things work (yes, I took things apart as a kid). Being open to learning new skills that are not just related to nuclear medicine technology has expanded my abilities and allowed me to become a valuable part of a world-class research operation.

One of the great things about research is seeing the development of new radiotracers and imaging techniques and evaluating their efficacy for potential use in a clinical environment. On a daily basis, I feel like I am on the front lines of the future of nuclear medicine, and it all began as a nuclear medicine technologist.

Research Essentials:
Financial Conflict of Interest in Clinical Trials

Excerpt from CTN course #112

As reported in "Conflict of Interest in Medical Research, Education, and Practice," published April 21, 2009, by the Institute of Medicine, "conflict of interest is a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest (promoting and protecting research integrity and the welfare of patients) will be unduly influenced by a secondary interest (financial gain, desire for professional advancement [publications, awards], or favors to friends, family, colleagues)." The Food and Drug Administration Code of Federal Regulations oversees financial conflicts of interest in clinical research and has set forth very specific guidelines as to what must be disclosed. This includes:

- Compensation made to the investigator in which its value could be affected by study outcome
- A proprietary interest in the tested product; i.e., patent or licensing agreement
- Any equity interest in the sponsor of a covered study; i.e., ownership interest or stock options
- Significant payments with a cumulative monetary value of $25,000 or more by the sponsor to the investigator or institution to support activities of the investigator (exclusive of clinical study costs)

Sponsors must obtain financial disclosure forms before permitting an investigator to begin participation in a study. All persons filing the conflict of interest disclosure must update their information if any relevant changes occur during the trial and for up to one year following completion of the study. The goal of this strict oversight is to promote objectivity in research so there is a reasonable expectation that the design, conduct and reporting of research funded are free from bias resulting from investigator financial conflicts of interest.

SNMMI and CTN Have a New Website

The newly-designed SNMMI website features a streamlined and user-friendly format for finding information on a wide-range of topics. One of those topics is research, and CTN is pleased to announce its new look along with updated information for the research community.

Our mission is to advance the use of molecular imaging radiopharmaceuticals in clinical trials through standardization of chemistry and imaging methodology. This includes using imaging radiopharmaceuticals during the course of drug development, as well as bringing new imaging agents to regulatory approval. We strive to provide the most up-to-date information on our projects and programs to assist imaging personnel, investigators and industry in performing high quality imaging for clinical research. The new website is formatted for ease of viewing on any device—desktop, tablet or smartphone. Take a moment and check it out at www.snmmi.org.

Tech **Tip**

BACK TO BASICS

Are you practicing imaging basics? Where allowed by the study protocol, follow these key tips:

- **Prevent Motion Artifact by Minimizing Patient Discomfort:**
  - Supply blankets for comfort, as warm patients are less likely to move and shudder/shiver than patients who are uncomfortably cold.
  - For comfort, place a pillow under the knees (lumbar support) or behind the neck to minimize motion.
  - Strap the arms to the abdomen so the patient can relax their arm muscles. If imaging must be done with arms overhead, support the arms with additional cushioning so arm muscles can relax.
  - For neuroimaging, supplement the headholder and chin strap with tape or self-adhering wrap such as Coban® across the forehead to keep the head in proper position preventing motion.
- **Standardization Across Sites:** Follow the protocol for incubation time, sound, light and temperature environment post-injection so data from patient to patient, and from site to site, are acquired under the same conditions.
- **Accurate Quantitation and Interpretation:** Center the patient horizontally, vertically and with regard to horizontal tilt.
  - Symmetrical and centered positioning is easier to reproduce from study to study in a single patient.
  - Regions of interest (ROI) are more reproducible when they incorporate the exact anatomy from image to image; imaging off-center or at a tilt might include tissue that should not be in the ROI.
  - An asymmetric appearance not due to pathology can confound interpretation. Similarly, if there is caudal/cranial tilt, the sequence of how structures and organs should appear is altered. The interpreter typically relies on symmetrical positioning to discern if any asymmetric uptake is due to disease process.

These techniques for high-quality data acquisition are critical in research imaging.

Clinical Trials Network
WEBINAR SERIES

CTN has finalized its 2014 webinar series to reach a global audience. Webinar topics include:

FEBRUARY 27
PK and Biodistribution Sampling in Clinical Trials (CTN Course 110)
Speaker: LisaAnn Trembath, CNMT, MSM, CCRA

APRIL 24
Standardizing CT for PET and SPECT Research
Speaker: Jonathon A. Nye, PhD

JUNE 26
PET Imaging of the Brain for Technologists
Speaker: Adam Opanowski, CNMT, PET, NCT, RT(N)

AUGUST 21
Using FACBC to Image Recurrent Prostate Cancer
Speaker: David Schuster, MD

OCTOBER 23
Updates on ^{68}Ga: Outlook for the Future
Speaker: David Dick, PhD

DECEMBER 11
Coverage with Evidence Development for Amyloid Imaging: Current Status
Speaker: Maria Carrillo, PhD, Alzheimer's Association

For the complete list of webinar titles and speakers please view CTN's educational offerings at www.snmmi.org/ctn.

Biomarker Spotlight Continued from page 5.

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Save the **Dates**

SNMMI 2014 Mid-Winter Meeting
Feb 6 – 9, 2014 • Palm Springs, CA

SoCRA Conference: FDA Clinical Trial Requirements, Regulations, Compliance and GCP
March 12 – 13, 2014 • Newport Beach, CA
May 21 – 22, 2014 • Indianapolis, IN

EANM Biomarker Summit 2014
March 19 – 21, 2014 • San Diego, CA

AACR Annual Meeting 2014
April 5 – 9, 2014 • San Diego, CA

ASCO Annual Meeting
May 30 – June 3, 2014 • Chicago, IL

SNMMI 2014 Annual Meeting
June 7 – 11, 2014 • St. Louis, MO

DIA 2014 50th Annual Meeting
June 15 – 19, 2014 • San Diego, CA

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