Clinical Trials Network: From Clinical Trials to Practice

Virginia Pappas, CAE, *SNMMI CEO*

In its 6-year history, the SNMMI Clinical Trials Network (CTN) has made significant progress in ensuring high-quality PET imaging in multicenter clinical trials. This increased standardization in trials is leading to better data, which will result in expanded utilization and ultimately regulatory approval of new radiopharmaceuticals. The CTN provides tools and resources to promote faster, more cost-effective drug development. These tools include a registry of qualified imaging sites and biomarker manufacturers, a robust scanner validation program, access to standardized imaging protocols, and clinical research education and training for site personnel.

The CTN PET/CT Scanner Validation Program has collected more than 400 sets of data from more than 230 unique scanners located at imaging sites around the world using its oncology clinical simulator phantom. The scanners include most commercially available PET/CT systems from the 3 main vendors, ranging from the older, basic models to the most current state-of-the-art systems. The overall set-up and management of this unique program, along with its acquired data, have led to interesting results that will be documented in articles submitted to *The Journal of Nuclear Medicine*. The first of these is "Quantitative PET/CT scanner performance characterization based upon the Society of Nuclear Medicine and Molecular Imaging Clinical Trials Network Oncology Clinical Simulator Phantom," by John J. Sunderland, PhD, and Paul E. Christian, BS, CNMT (*J Nucl Med.* 2015;56:145–152), which describes the quantitative variability observed in multicenter clinical trials and discusses methods to help minimize this variability.

One of the goals of the CTN Strategic Plan is to provide education to imaging personnel who are involved in clinical research, including physicians, technologists, and physicists. To that end, the CTN has developed a course curriculum of 17 courses that cover the gamut of research from beginner courses on The Language of Clinical Trials to more advanced topics such as Pharmacokinetic and Biodistribution Sampling in Clinical Trials. Each year the CTN Webinar Series offers 6 live webinars on hot topics in research presented by the field's top experts. This year's offerings include presentations on the Cheson Criteria for Lymphoma and Dynamic PET Imaging, among others. CTN also offers educational sessions at the SNMMI Mid-Winter and Annual meetings. This June, CTN will partner with SNMMI's Committee on Outreach to present a full-day categorical course on Advances in Prostate Cancer: Diagnosis, Treatment, and Management. All online and live courses and webinars offer continuing medical education credit.

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In 2012, CTN formed the Gallium Users Group to advance the use of gallium-labeled somatostatin receptor–targeted imaging agents. After deciding to develop tools for a generic ^{68}Ga-labeled somatostatin receptor rather than focusing on a single agent, the group produced template study documents so that individual sites could choose which agent to study. The group has since developed harmonized release criteria, a template Investigational New Drug application, an imaging protocol/manual, and case report forms and has collated information on how to develop a cost recovery program. In 2012, 2 sites in the United States used the agents; as of August 2014, 12 active sites used the agents, with 9 more pending IRB approval. SNMMI also received orphan drug designation for ^{68}Ga-DOTATOC.

SNMMI is excited to collaborate with the Johns Hopkins University for the 3rd Theranostics World Congress on ^{68}Ga and peptide receptor radionuclide therapy (http://www.wcga68.org), which will be held in Baltimore, MD, March 12–14. CTN has been integrally involved in the coordination of this meeting. Although widely used in Europe, ^{68}Ga PET radiopharmaceuticals have been used in the United States only in investigational trials under INDs. With the potential of an approved agent available in the near future, this conference will be beneficial to those who are new to this class of agent and want to learn more from experts from around the globe.

As CTN enters its seventh year with exciting projects underway, we also look forward to the new initiatives of the future. I would like to thank Bonnie Clarke, director of the CTN, along with her staff members Tina Kiss and Jina Kim, and CTN co-chairs Michael Graham, PhD, MD, and John Hoffman, MD, for their continuous efforts and support of the program. We plan to continue our efforts in collaborating with new and varied industry partners to work on projects that will benefit the molecular imaging community.