# Clinical Trials Network Update

*Virginia Pappas, CAE, SNMMI CEO*

The Clinical Trials Network (CTN), which SNMMI formed in 2008, has made significant progress in ensuring high-quality PET imaging in multicenter clinical trials, which will result in expanded utilization and ultimately regulatory approval of new radiopharmaceuticals. As it approaches its seventh anniversary, the CTN is holding a stakeholder meeting to evaluate progress and future needs. Following are some highlights of its current activities.

The CTN sees itself as a prestudy clinical research organization; we help pharma and academic investigators put the tools in place for successful conduct of an imaging trial. This includes ensuring access to investigational radiotracers, validating the quantitative and qualitative accuracy of the scanners to be used in the trial, and educating staff on proper image acquisition and reconstruction. The education component of the CTN sets it apart from other organizations in that it offers a complete imaging curriculum for physicians and technologists performing clinical trials.

The CTN's comprehensive database currently contains more than 400 registered imaging and production sites, including those with both capabilities. It contains all cyclotron facilities in the United States and the radiopharmaceuticals each makes, the regulatory auspices under which they are made, how often, and the sites' willingness to allow cross-referencing. The plan is to continue the expansion to the rest of the world. For imaging-only sites, captured information includes personnel, scanner and radiopharmaceutical availability, research infrastructure, and institutional review board information.

The CTN operates a PET/CT phantom imaging program utilizing its oncology clinical simulator or phantom. This Scanner Validation Program has now captured more than 500 scans from more than 260 scanners that have been validated worldwide. The resulting bank of data allows the CTN to advise sites on ways to improve a scanner's lesion detection ability or quantitative performance. The CTN is coordinating a 5-year, $2.6 million initiative funded by the National Institutes of Health and begun in September 2012 in response to the need for better quantitative harmonization. The program is working to identify optimized and harmonized PET reconstruction parameter sets for all recent model PET/CT scanners. Scientists and engineers from GE, Philips, and Siemens are actively contributing to the project.

The CTN manages the $^{68}$Ga Users Group, which was formed to advance the use of $^{68}$Ga-labeled somatostatin receptor imaging agents in the United States. Members of the group developed harmonized release criteria, an imaging manual, and generic data collection forms to aid the community in establishing investigator-sponsored trials. The group was the first entity in the United States to receive orphan drug designation from the U.S. Food and Drug Administration for $^{68}$Ga-DOTATOC, in October 2013.

In March 2015, SNMMI and Johns Hopkins cosponsored the Third Theranostics World Congress on Gallium-68 and Peptide Receptor Radionuclide Therapy at the Johns Hopkins Medical Institutes Campus in Baltimore, MD.

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The Nuclear Medicine Clinical Trial Group (NMCTG), set up by SNMMI, aims to ensure that high-quality imaging is conducted to support drug or diagnostic clinical studies by offering a variety of proven tools developed by CTN, including: education and training for molecular imaging professionals performing clinical research, a robust PET scanner validation program to ensure scanner stability at individual study sites and help standardize PET imaging across sites in a study, a secure central image and data management platform, and auditing of radiopharmaceutical manufacturing sites to ensure the safety of study patients by monitoring production of the investigational imaging agent being used.

NMCTG currently has a grant for management of 2 international, multicenter, academic trials in prostate cancer imaging from Movember (East Melbourne, Australia). Both studies are using the Scanner Validation Program for qualification and Keosys Imagys platform for image and data collection. The first study utilizes $^{18}$F-choline PET/CT in preradiotherapy PET/MR imaging for postprostatectomy salvage; the second is an evaluation of androgen receptor expression in progressive metastatic prostate cancer patients using $^{18}$F-dihydro-testerone PET. Each study is in its second of 2 years.

The CTN is continuing to harness data already published and working to identify opportunities to help nonproprietary imaging agents toward approval. The community is anticipating the approval of 3 new nuclear agents next year. CTN is working to continue this trend. In addition, the CTN, in collaboration with the National Cancer Institute, will convene an Imaging in Immunotherapy think tank to begin to address the critical, unmet clinical need of assessing response to immunotherapy agents.

Quality of care is always our foremost concern. Faster, more cost-effective drug development means greater patient access to life-saving diagnostics and treatments. Employing the tools developed by CTN can make this possible. The CTN is on the leading edge of molecular imaging research and continues to creatively develop solutions to advance the use of new agents in research and in the clinic. If making a difference is important to you, the CTN welcomes new committee members. If you need assistance with an imaging trial, please contact CTN at ctnadmin@snmmi.org.