

SNMMI CLINICAL TRIALS NETWORK

Committee Report
SNMMI Board of Directors
January 2015

Highlights:

- The Clinical Trials Network (CTN) continues to work on 7 different investigational agents being used in trials or in drug development projects.
- Three papers based on the results of the CTN chest phantom program and scanner validations were submitted for publication 4Q2014
 - Quantitative PET/CT scanner performance characterization by John Sunderland (lead author) was **published in JNM - January 2015**
 - The CTN chest phantom program experience by Paul Christian (lead author) was accepted with revisions for future JNM publication
 - Comparison of three PET phantoms for spatial resolution by Lance Burrell (lead author) was submitted to JNM as a brief communication
- Efforts by the Gallium Users Group to facilitate approval of Ga-68 labelled somatostatin receptor agents in the US have resulted in increased use of these agents in investigational studies. There are currently 12 active sites with an IND and 5 additional sites pending IND approval. A number of these groups used the Ga68-DOTA-XXX template documents developed by the Gallium Users Group and available on the CTN website in their applications to the FDA.
- The Orphan Drug Designation for DOTATOC initially granted to SNMMI in October 2013 has been successfully transferred to the University of Iowa Department of Radiology PET Center. They will pursue an NDA for DOTATOC.
- This past November, Bonnie Clarke presented a talk titled “Clinical Trials Network: Facilitating Multicenter Trials” at the Japanese SNM Annual Meeting in Osaka, Japan and presented to industry executives in Yokohama on the topic “Keys to Success in Using PET in Clinical Trials”.

CTN completed 2014 having successfully met a number of its goals:

- The Gallium Users Group, formed in 2012 to advance the use and approval of Gallium-labelled somatostatin receptor-targeted imaging agents in the US, finalized revisions to its IND application document templates, which are available on the CTN website. These documents include harmonized release criteria, a template Investigation New Drug application (IND), imaging protocol/manual, case report forms (CRFs) and collated information on how to develop a cost recovery program.
- Scheduled CTN database revisions were completed as planned, and the Database Reporting Tool (DaRT) rolled out its upgraded version that links directly to the new CTN Database. Both tools have enhanced search functions and reporting capabilities, and the database has the ability to perform a more detailed analysis of the collected data, including scanner validation results.
- Members of the SPECT Committee are concentrating efforts to develop parameters and guidelines for data collection and analysis for validating cardiac SPECT phantoms. A list of SOPs for the Committee was drafted, with priority assigned to personnel training and image review.

- The Site Education Committee developed two new “100” level courses designed for Technologists, but with relevance for other imaging personnel:
 - #118 CT Basics for PET/CT in Clinical Trials: to be presented at 2015 MWM and as a CTN webinar in June 2015
 - #120 Dynamic PET Imaging for Technologists: CTN webinar on February 19, 2015
- CTN published the January 2015 *Pathways* issue, which will be available at the 2015 Mid-Winter Meeting. Key articles include “PET in Prostate Cancer: Focus on C-11 Choline” and “C-11 Choline Pathway to NDA Approval.”
- The Scanner Validation Committee completed initial testing of a new chest phantom that contains the same number and lesion sizes as the NEMA NU-2 phantom. Minor modifications are being discussed, with the final version anticipated for use in 2Q2015. Active studies will continue to use the current CTN phantom until those studies are completed. New projects requiring scanner validations will use the updated model once available.

Looking forward to 2015, CTN anticipates a very busy year. A number of projects from last year are being carried over, and additional projects are already planned or on the horizon. These include:

- CTN plans to apply for a PCORI (Patient-Centered Outcomes Research Institute) grant to collect and analyze change in patient management data collected from the sites studying 68Ga-labelled somatostatin receptors.
- Dr. John Sunderland (Chair, Database Committee) and Dr. James Mountz (Chair, Site Qualification and Monitoring Committee) are preparing a grant for submission to the NIH in response to a request for academic/industry partnerships on to accelerate the translation of clinical in vivo imaging systems and/or methods that are designed to solve a targeted cancer problem. The role of CTN in this project will be defined as the application progresses.
- Additional papers are planned based upon the results of the CTN chest phantom scanner validations. An abstract on phantom failure occurrences is being submitted for presentation at the SNMMI 2015 annual meeting, and a paper on CT dosimetry is planned for submission to a peer-reviewed journal in 2Q2015.
- The SNMMI and Johns Hopkins University are co-sponsoring the 3rd Theranostics World Congress on Ga-68 and PRRT being held in Baltimore, Maryland on March 12-14, 2015. Abstract submission closed December 10, with 97 of the submitted 102 abstracts accepted for oral or poster presentations. CTN staff will play a very active role onsite during the meeting.
- The Radiopharmaceutical Manufacturers Committee plans to conduct both on-site and desktop audits of the PET production sites manufacturing FLT for the ongoing BMS study that cross-references the SNMMI-held FLT IND.
- CTN continues to provide support for the 5-year NIH R01 grant on harmonizing PET reconstructions for cancer clinical trials. Staff assists academic centers with phantom scanning, oversees image upload and management in the Keosys Imagys server and provides general administrative report. Investigators will submit for the grant’s fourth year of funding.
- As part of its ongoing collaboration with EANM/EARL, CTN hopes to finalize harmonizing specific areas of these two scanner validation programs in an effort to standardize PET imaging on a more global front.

CTN continues to investigate ways to collaborate with other groups and industry partners on projects that benefit the entire molecular imaging community. Funding will be sought to support expansion of its Educational Program to include higher level, scientific offerings developed by experts in the field, and efforts to improve standardization and the quality of PET imaging in clinical research will remain a key activity for the CTN Phantom Program and Scanner Validation Committee.