

SNMMI CLINICAL TRIALS NETWORK

Committee Report SNMMI Board of Directors September 2014

Highlights:

- FDA has cited the work of the Gallium Users Group, staffed by CTN, when reviewing and replying to official correspondence and applications from other companies. Of note, the Ga68-DOTA-XXX release criteria were referenced.
- The CTN continues to work on 7 different investigational agents in trials or in drug development projects.
- The manuscript on “Quantitative PET/CT Scanner Performance Characterization” by John Sunderland was submitted to JNM for publication. This work reports quantitative data analysis from over 400 phantom scans on more than 200 unique scanners around the world using the CTN oncology phantom. Several more manuscripts on the phantom data and program status are being written.
- The efforts of the Gallium Users Group have resulted in 12 active sites in the US imaging with Ga-68 labelled somatostatin receptor agents, with 9 additional sites pending approval of INDs.
- The CTN will have a Type B Meeting with FDA on November 4th to discuss filing an NDA for Gallium-68 DOTATOC.

The Clinical Trials Network (CTN) held their Operations Committee Retreat in Salt Lake City, Utah on August 1-3, 2014. The meeting was extremely successful and resulted in the following:

- The new SPECT committee will work on guidelines to help train physicists and sites meet the July 2015 Joint Commission guidelines.
- The Scanner Validation committee will move forward with the development of a new chest phantom that contains the same number and lesion sizes as the NEMA NU-2 phantom. This will achieve better standardization with European groups, namely EARL.
- The CTN database upgrades are being finalized. The Radiopharmacy Science Council of the EANM plan to add their sites and supply RP information in the CTN database.
- The Site Education Committee will develop a set of higher– “200 level” – set of courses for physician, physicists and scientists. The goal for completion is 18 months, with launch expected at the SNMMI 2015 Annual Meeting. Proposed topics include:
 - Statistics for Imaging Scientists
 - Monitoring in Clinical Trials
 - Phases of Drug Development
 - Training Module on RECIST and PERCIST Measurements
 - PET QC and Equipment Standardization in Clinical Trials

The CTN webinar series continues with plans for the 2015 series underway. The 2014 webinars include:

- PK and Biodistribution Sampling in Clinical Trials – *LisaAnn Trembath, CNMT, MSM, CCRA*

- Standardizing CT for PET and SPECT Research – *Jonathon Nye, PhD*
- PET Imaging of the Brain for Technologists – *Adam Opanowski, CNMT, PET, NCT, RT(N), and LisaAnn Trembath, CNMT, MSM, CCRA*
- Using FACBC to Image Recurrent Prostate Cancer – *David Schuster, MD*
- Updates on Ga-68: Outlook for the Future – *David Dick, PhD*
- Coverage with Evidence Development for Amyloid Imaging: Current Status – *Maria Carrillo, PhD*

The CTN newsletter “*Pathways*” is published twice a year with articles written by a variety of authors on timely topics. Additionally, two members of the CTN Site Education Committee submitted an article for the September/October *Uptake* newsletter, and another article is being prepared by three co-authors for submission to JNMT. The CTN also provided speakers for the 2014 Technologist RoadShows. The theme was “Broadening the Professional Horizons of Nuclear Medicine Technologists” and CTN speakers presented a one-hour lecture as part of the four-hour CE session held in 6 different cities.

CTN continues to collaborate with EANM to develop a joint EU/US regulatory course, a white paper on Promoting PET imaging in Trial Design, and scanner validation programs.

In 2012, the Clinical Trials Network (CTN) formalized the Gallium Users Group, a work group formed to advance the use of Gallium-labelled somatostatin receptor-targeted imaging agents. The group had loosely formed in 2011 and met infrequently. In 2012, the SNMMI Board of Directors approved the group under the CTN and appointed co-chairs Michael Graham, PhD, MD and Ronald Walker, MD. After deciding to develop tools for a generic Ga-68 labeled somatostatin receptor versus focusing on one agent, the Users Group made the decision to develop generic study documents so that individual sites could choose which agent to study. To that end, the Group developed 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. Of note, in 2012 there were 2 sites in the US using these agents (Vanderbilt and University of Iowa). As of August 2014, there are now 12 active sites and 9 pending approvals.

The SNMMI will co-sponsor with the Johns Hopkins University on the 3rd Theranostics World Congress on Ga-68 and PRRT to be held in Baltimore, Maryland on March 12-14, 2015. CTN has been integrally involved in the meeting to date.

The R01 grant, Harmonized PET Reconstructions for Cancer Clinical Trials, continues in its third of 5 years. CTN supports this effort with staff time, use of the Keosys Imagys system for image storage, and general administrative report. We are currently exploring an expansion of the grant to an industry/academic U01, utilizing the new version of the phantom.

Lastly, CTN plans to work with the SNMMI Development Department to apply for a renewal of the Genentech Foundation grant in October 2014.

CTN enters its seventh year with exciting projects underway and new ones on the horizon. We plan to continue our efforts to collaborate with new and varied industry partners to work on projects that will benefit the entire molecular imaging community.