

SNMMI CLINICAL TRIALS NETWORK

Committee Report SNMMI Board of Directors September 2015

Highlights:

- The Clinical Trials Network (CTN) continues to work on 7 different investigational agents being used in trials or in drug development projects. These include FLT, DOTATATE, DOTATOC, FDHT, F-Choline, Fluciclovine, and HX-4.
- Efforts by the Gallium Users Group to facilitate approval of ⁶⁸Ga-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.
- An NDA for Ga-DOTATATE has been filed by AAA.
- CTN developed a new version of the oncology chest phantom. The torso contains the same number of and sized lesions as the NEMA phantom. The new model is currently being characterized by the Scanner Validation Committee members.

Current projects of the CTN include:

- The upgraded 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. A complete data refresh is underway. Additionally, new sites outside of the US are being added, especially manufacturing sites. This information is being used by the Global Initiative.
- 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.
- 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.

CTN held its annual Operations Committee Retreat in August. SNMMI BOD leadership attended. The CTN mission and goals were updated.

Vision: The CTN will take a leadership role in advancing the use of molecular imaging and radiotherapeutic agents, optimizing their use in clinical trials for translation and dissemination into clinical practice.

Mission: Facilitate the effective use of MI in clinical trials through standardization, coordination, and education for drug development and regulatory approval.

Goals:

1. Ensure high quality PET and SPECT imaging in the conduct of therapeutic drug development clinical trials
2. Facilitate the use and approval of new radiopharmaceuticals
3. Improve access to investigational radiopharmaceuticals for multicenter clinical trials
4. Provide education and training for the use of molecular imaging in clinical research
5. Ensure fiscal sustainability
6. Broaden leadership, committee membership, and technical staff with additional knowledgeable members.

A fund-raising plan for CTN was also developed. CTN will hold one to two meetings with pharmaceutical companies to update them on the programs that have been developed by CTN and how we can work together. The meeting will be scheduled for early November 2015 or February 2016. CTN will continue to investigate and apply for foundation and grant funding for general program support. Lastly, the CTN will convene a conference on Imaging in Immunotherapy, which currently poses a problem for conventional imaging. A NCI Conference grant will be sought.

CTN continues to investigate ways to collaborate with other groups and industry partners on projects that benefit the entire molecular imaging community. CTN has been asked by the NCI Imaging Program, namely Paula Jacobs, to build a tool for connecting IND holders of PET drugs with potential would-be investigators. This site would eventually house INDs and other regulatory documents for ease of sharing and collaboration.