

SNMMI CLINICAL TRIALS NETWORK

Committee Report
SNMMI Board of Directors
June 2014

CTN VISION

The CTN will take a leadership role in advancing the use of radiopharmaceuticals and optimizing the use of molecular imaging in clinical trials and dissemination into clinical practice.

CTN Mission

Advance the use of molecular imaging biomarkers in clinical trials through standardization of chemistry and imaging methodology. This includes using imaging biomarkers during the course of drug development, as well as bringing new radiopharmaceuticals to regulatory approval.

The first half of FY 2014 has been very busy for CTN. To simplify and address the increasing business interactions with commercial entities, the SNMMI/CTN reinvigorated the Nuclear Medicine Clinical Trial Group, LLC (NMCTG). All contracted study activities are conducted through NMCTG. Some of the key accomplishments for both groups include:

CTN

- Requested a meeting with the FDA regarding filing an NDA for Gallium-68 DOTATOC; proposed early July meeting date
- Assisted NIBIB with a survey of research sites and radiopharmaceutical manufacturers on their need for research medical isotopes
- The CTN database has been amended to include additional fields requested by NCI. CTN will partner with RPSC and EANM to include all manufacturing sites in Europe in the database. Additionally, CTN has started an active campaign to refresh all of the US data in the database. This will be done annually.
- CTN has worked with HPRA on the FDA Task Force and Stakeholders Meeting.
- CTN has assisted the Coalition for PET Drug Approvals conduct a survey on FDA inspections for PET drug NDAs and aNDAs. This data is being presented on Monday June 9th.
- 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.
- The CTN Education Committee continues to develop live talks for the AM, MWM, road shows, and webinars plus higher level courses on specific topics in imaging research.
- Plans to co-host the 3rd World Congress on Gallium in 2015 with Johns Hopkins University are underway, pending an agreeable budget and memorandum of understanding.
- Validating scanners at three new industry studies contracted under NMCTG. A fourth study, already ongoing under CTN, recently added two new imaging sites and an additional FLT manufacturing site.

NMCTG

- Awarded a contract from Movember to oversee two international prostate cancer imaging trials
- Submitted a proposal to Blue Earth Diagnostics to assist with a “consensus read” meeting in June 2014
- Multicenter center study underway with Threshold Pharmaceuticals using the HX4 imaging agent

Gallium 68 Update - The Gallium User’s Group meets monthly via conference call to discuss the current situation of and future outlook for the approval of these peptides for PET imaging. Most recently, a letter has been sent to manufacturers of the precursor to ask them to consider lower pricing for pre-clinical imaging and patient imaging in clinical research studies. The recent extraordinary rise in pricing is negatively affecting current activities and is discouraging future development of the drugs.

The SNMMI Mid-Winter Meeting in Palm Springs, California held a Gallium Information Session that was well-attended by industry and investigators, and another session is scheduled for the Annual Meeting in St. Louis.

CTN was approached by past hosts of the World Congress on Gallium to see if it could assist in hosting the 2015 meeting in the United States. Johns Hopkins University has offered to co-host the event and is preparing an MOU and other documents for review by SNMMI Board and CTN. The proposed date of this 3rd World Congress on Gallium is March 12-14, 2015.

Movember Update - NMCTG was awarded a contract from Movember to oversee two Movember-funded trials using novel PET agents to image prostate cancer. One trial will study ¹⁸F-Choline and one, FDHT. Investigators at 14 sites on 3 continents are involved in this international effort. CTN’s Imagys system is being used to manage both imaging and clinical data. Study sites have access to electronic case report forms and the imaging viewer to enter data and upload study images. A central reading group in Australia will then be able to view all uploaded images and also download them to a local station for further analysis. F-Choline study site personnel are currently being trained on using the Imagys system with a planned start date in June 2014. The FDHT trial study group is meeting at the SNMMI 2014 Annual Meeting to finalize study procedures and plan study start-up mid-summer 2014.

Industry

The NMCTG is working with Blue Earth Diagnostics, a newly-formed company, to develop ¹⁸FACBC (fluciclovine). The first task will be to assist with a meeting of current investigators to develop a consensus on how FACBC images should be read and reported.

Threshold Pharmaceuticals has hired NMCTG to assist them in their study using HX4, an investigational PET agent, in a metastatic melanoma trial. The contracted services include CTN scanner validation, image quality assurance and providing education for imaging site personnel. Six sites in the US and Canada are in varying stages of start-up, and training of the centers are scheduled for the last week in May 2014.

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