



SNMMI Nuclear Medicine Clinical Trial Group, LLC

January 2016

Highlights:

NMCTG is conducting an expert reader meeting for AAA of ^{68}Ga -DOTATATE. This material will be used in reader training programs offered through SNMMI.

NMCTG was asked to submit a proposal to EANM for an expert reader meeting for ^{68}Ga -PSMA for prostate cancer imaging. This meeting is scheduled for summer 2016.

NMCTG has submitted a proposal to a start-up company for a novel imaging agent; they would like assistance in getting an IND.

The following sponsored studies are currently using NMCTG services:

Movember (Australia)

NMCTG is providing clinical management for two international, multicenter, academic trials in prostate cancer imaging being funded by the Movember Foundation. Both studies use the Keosys Imagys platform housed at the SNMMI home offices (Reston, VA) for image upload and storage. Electronic Case Report Forms (eCRFs) have been developed for both studies, and sites complete the required forms in Imagys to record clinical trial data. The NMCTG is using CTN's unique oncology chest phantom to perform annual scanner validations on all PET/CT scanners used to scan study patients. The timeframe for both studies is planned for two years.

Study 1: PET / MRI Pre-Radiotherapy for Post-Prostatectomy Salvage (PROPS):

- Tracer: ^{18}F -Choline
- Enrollment underway
- 145 subjects plan to be enrolled and have at least one ^{18}F -Choline PET/CT scan and one MRI
- PET Central Reading/Analysis: Peter MacCallum – Australia
- MRI Central Reading: University College London – England
- Ten recruiting sites (nine imaging centers) located in Australia, Canada and the UK

Study 2: Evaluating AR (Androgen Receptors) Expression in Progressive Metastatic Prostate Cancer Patients Treated with an Anti-androgenic Drug

- Tracer: ^{18}F -DHT
- Enrollment start-up is pending finalization of the MRI review process and completion of case report forms.
- 105 subjects plan to be enrolled and have ^{18}F -DHT PET/CT scans and MRI done at two time points



- Both PET and MRI images are uploaded into Imagys, with the review and analysis conducted locally. Site reports are sent to Movember for final analysis.
- Four recruiting sites/imaging centers, one each in Australia, the Netherlands, England and the US.

Bristol-Myers Squibb (United States)

- Title: Phase 1 Ascending Multiple-Dose Study to Evaluate the Safety, Pharmacokinetics and Pharmacodynamics of BMS-906024 in Subjects with Advanced Solid Tumors
- Tracer: ^{18}F -FLT (the study cross-references the SNMMI-held FLT IND)
- Over 98 subjects have been enrolled over 5 years; the study has recently been extended through 2016.
- Subjects are scheduled to receive an ^{18}F -FLT PET/CT scan at baseline and post-treatment.
- PET Central Reading/Analysis: PAREXEL Informatics – United States
- Seven sites are currently enrolling patients. Sites are located in Australia, Canada and the US.

NOTE: This study was initially managed under CTN through start-up funding from BMS as one of CTN's three founding sponsors. It is now administered under NMCTG as a fee-for-service study.

Threshold (United States)

- Title: A Phase 2 Study of TH-4000 in Patients with EGFR-Mutant, T790M-Negative, Advanced Non-Small Cell Lung Cancer Progressing on an EGFR Tyrosine Kinase Inhibitor
- Tracer: ^{18}F -HX4 (for hypoxia)
- Approximately 37 subjects are scheduled to receive one ^{18}F -HX4 PET/CT scan at baseline
- Seven sites in the US.

Other drug development projects are underway with Advanced Accelerator Applications (AAA) and Blue Earth Diagnostics. NMCTG staff and members continue to look for new opportunities to collaborate.

Background:

SNMMI created the Nuclear Medicine Clinical Trial Group, LLC (NMCTG) in 2005 to assist industry partners and academic investigators in managing clinical research activities. Its goals include ensuring quality imaging is conducted in drug or diagnostic clinical trials and providing training for molecular imaging professionals performing clinical research. Many of the programs established under the SNMMI Clinical Trials Network (CTN), such as its robust Education Program and Scanner Validation (Phantom) Program, provide support to the NMCTG to help carry out its mission.

In March 2015, the Operating Agreement for the NMCTG was updated to reflect more current activities and to revise the management structure. Michael Graham, PhD, MD will be the Chair and John Hoffman, MD will be the Vice-Chair of the NMCTG. Members of the SNMMI BOD executive committee round out the Management Board.



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The day-to-day activities of the NMCTG will be managed by the Operations Committee. This committee consists of the Chair and Vice-Chair, Sally Schwarz, the chairs of most of the CTN committees. The Finance Committee will be chaired by Mike Middleton and will include SNMMI CFO Vince Pistilli.