

SNMMI CLINICAL TRIALS NETWORK

Committee Report
SNMMI Board of Directors
February 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 quarter of FY 2014 has been very busy for CTN. Some of the key accomplishments include:

- CTN was awarded a ~1.4 million USD grant from Movember for a prostate cancer imaging trial using FACBC.
- An Investigator Sponsored Study for FACBC in prostate cancer imaging was approved for \$617,000
- ⁶⁸Ga-DOTATOC was granted Orphan drug Status by the FDA

Movember Update - CTN has been pursuing a prostate imaging grant from Movember, an Australian group promoting men's health. A consortium of 8 international sites plus the CTN, has conditionally secured a \$1.48 million USD grant to conduct a post-prostatectomy prostate cancer imaging study using ¹⁸F -FACBC. The total cost of the trial is in excess of the Movember funding so additional funding was sought from GE Healthcare, the patent holder of the agent. GEHC approved the funding of \$617,000. Of note, GEHC has received a large sum of venture capital for FACBC, so this portion of the project is currently on hold.

In addition to FACBC, CTN received a grant from Movember to oversee two additional Movember-funded trials. Those trials will study ¹⁸F-Choline and FDHT and involve 14 sites on 3 continents. CTN's Imagys system will be used to manage imaging and clinical data. The studies will start in 1Q2014.

Gallium User's Group Update – The CTN filed an application for Orphan Drug Designation for ⁶⁸Ga-DOTATOC on August 14th. Orphan Drug Designation was granted on October 29th. The press release has generated a lot of interest and CTN leadership has several meetings set up during MWM with companies who are interested in the development of Gallium-labeled imaging agents. Initially, CTN planned to apply for orphan drug status for DOTATATE, however, two companies have already done so (RadioMedix and AAA). CTN is exploring whether this is a worthwhile endeavor.

CTN Database - The CTN database was upgraded to include several key new fields. The upgraded database, version 2.0, went live on November 8th. DaRT, the database reporting tool, has been updated as well.

CTN has formed a SPECT Committee which is chaired by Jonathan Nye, PhD from Emory University. The remaining members of the committee are being finalized.

CTN finished its fifth year in a financially stable position and continues to collaborate with new and varied industry partners. New and exciting projects are being developed that will benefit the entire molecular imaging community. With the new strategic plan in place, the CTN looks forward to fulfilling its mission and goals.