

Clinical Trials Network Strives for Standardization

By Michael Graham, PhD, MD; Peter Conti, MD, PhD; and John Hoffman, MD

Two meetings geared at generating industry-wide standardization were held during the SNM 2010 Annual Meeting in June: the FDG Protocol Worldwide Summit and the Image Reconstruction Harmonization Group (IRHG) meeting.

FDG is the most commonly used radiopharmaceutical in clinical oncology PET studies and is used in numerous clinical trials. In clinical trials, it is important to conduct the studies in a standardized fashion that facilitates accurate interpretation of the study data, particularly when compared to similar trials. In an effort to create one protocol that would be widely acceptable for virtually all oncology clinical trials incorporating FDG imaging, the SNM Clinical Trials Network (CTN) convened a meeting with 25 representatives from key groups around the world. Using the summary document developed by the UPICT group, we addressed a number of key items and completed review of approximately three-fourths of the proposed topics. The discussion produced agreement on several significant points including management of diabetic patients, a minimum fasting time of 6 hours and a target imaging time at 60 minutes (55-75 min). Once all remaining points have been discussed and agreement reached, the final protocol will be organized into a jointly-authored document and submitted for publication.

The IRHG was formed in early 2010 to develop a strategy to harmonize PET image reconstructions used in clinical trials. The members, consisting of physicists from CTN, QIBA, and EANM, met with high-level physicists and engineers from each of the three major scanner vendors. For each PET/CT scanner model and vendor, the IRHG is providing raw scan data of the CTN oncology chest phantom and the NEMA image quality phantom. Vendors are charged with identifying reconstruction parameters resulting in image sets that are both quantitatively and qualitatively harmonized, with their own product line and also with other vendor's systems. The resultant model will allow all vendors to provide a clinical trial special reconstruction option in addition to the standard clinical imaging reconstruction. We anticipate that the success of this group's work should position PET imaging positively in the eyes of FDA and other regulatory bodies as it pertains to multicenter trials.