Ensuring Standardization and Harmonization in Multicenter Clinical Trials

An important aspect of any multicenter clinical trial involving an imaging modality is ensuring that the equipment used in the various locations is capable of acquiring images in a standardized fashion. A key feature of the SNM Clinical Trials Network registry is the capacity to ascertain and sustain the qualification of each of the many centers involved through a demonstration of their ability to acquire and interpret high-quality images. Toward this end, SNM will rely on its long-established imaging phantom program.

The SNM phantoms are sophisticated clinical imaging simulators based on proprietary designs. Successfully scanning these phantoms is part of the overall process that the Clinical Trials Network will use to validate imaging sites for future clinical trials. Imaging of the PET phantoms, which contain a known quantity and distribution of radioactivity, will be used to evaluate each site's imaging capabilities, both qualitatively and quantitatively. This will ensure standardization and compliance with defined protocols in order to achieve consistency across multiple centers in a single trial.

A new oncology phantom designed specifically for the network will help quantify how an imaging center acquires, processes, and displays images, as well as how successfully physicians interpret them. Cardiac and brain phantoms also are being developed for the network. Use of these phantoms will allow the Clinical Trials Network to ensure that all sites involved in a specific trial will meet the necessary standards for image quality and disease detectability.

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The SNM phantom program provides a distinct advantage in that it is made up of a group of experts who know what to look for when evaluating a center's image quality and can recommend adjustments in image acquisition parameters to produce very high-quality images. This is particularly important because many U.S. Food and Drug Administration (FDA) submissions are denied based on a rejection of data compiled from poor-quality images or images that do not appear to match those from another, similar study.

Standardization of adherence to protocols and harmonization of results are critical to compiling a body of significant data and, ultimately, to obtaining FDA approval. SNM's phantom program has already demonstrated its ability to establish compatibility in image quality and, therefore, present significant results. Use of the phantoms by the Clinical Trials Network offers a substantial enhancement toward ensuring that the FDA will accept the network's data, a major hurdle in drug approval. SNM's Phantom Program will be on display at the 2009 Annual Meeting in the MI Gateway in the Exhibit Hall.

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