SNM Molecular Imaging Summit Introduces Clinical Trials Network

More than 150 experts from molecular imaging, regulatory agencies, and the pharmaceutical industry came together on February 8 and 9, immediately after the SNM Mid-Winter meeting in Clearwater, FL, to advance the use of imaging biomarkers in multicenter drug development trials. The intensive 2-d workshop was organized by the SNM Molecular Imaging Center of Excellence and the SNM Clinical Trials Network leadership. The objectives were to discuss the need for imaging biomarkers in the development of therapeutic pharmaceuticals, to examine the challenges of imaging in multicenter trials, and to discuss the path forward to successful biomarker imaging for large multicenter clinical trials.

The summit was an opportunity to learn how SNM's new Clinical Trials Network can facilitate faster and more cost-effective drug and biologics development through improved integration and standardization of imaging biomarkers into Phase 1, 2, 3, and 4 therapeutic clinical trials. The workshop outlined details of clinical sites' participation in the network and examined the critical need for imaging standardization and harmonization across clinical trial sites.

Gustav von Schulthess, MD, kicked off the meeting with a keynote address highlighting the importance of choosing the appropriate imaging modality and biomarker to address the clinical question being evaluated in the therapeutic clinical trial. He also emphasized the need for standardization of imaging protocols between different imaging centers and different types of imaging equipment (different vendors or performance levels).

The formal program for the meeting then continued with a series of presentations highlighting both the needs and challenges associated with incorporating imaging into clinical trials. Of particular interest were presentations by pharmaceutical developers, including Diane Jorkasky, MD (formerly of Pfizer); Jeff Evelhoch, PhD (Merck); Dan Skovronsky, MD, PhD (Avid); Sudha Kadiyala, PhD (Advanced Technologies & Regenerative Medicine, a subsidiary of Johnson & Johnson); and Susan Galbraith, MB, BChir, PhD (Bristol-Myers Squibb). U.S. Food and Drug Administration (FDA) participants also shared their perspective on challenges they have experienced with the use of imaging biomarkers in multicenter clinical trials.

After listening carefully to the needs of these varied but interconnected communities, leaders of the Clinical Trials Network have focused on the issue of standardization of imaging protocols between and across multiple imaging centers participating in clinical trials. The Clinical Trials Network will work to ensure the use of a consistent methodology and protocol across the multiple clinical trial sites, which is key to quality data generation and ultimate FDA approval of investigational therapeutics and imaging diagnostics.

The network is encouraging imaging centers and PET radiopharmaceutical manufacturers to get involved at this time in order to maximize the impact of the network standardization programs.

A complete list of presentations is available at www.snm.org/clinicaltrials. Additional educational sessions are planned during the SNM Annual Meeting this June in Toronto.

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(Continued from page 17N)

increase availability of ^{99}Mo for generator production. After the recent release of the National Academy of Sciences panel report on low-enriched uranium (LEU) for ^{99}Mo production and with the U.S. presidential election and musical chairs of committee assignments in Congress now over, we are starting a program to educate stakeholders in Congress and the executive branch on the current crisis. Some bright spots have appeared, including the announced partnership of Covidien with Babcock and Wilcox and continued progress at the Missouri University Research Reactor on developing an LEU process.

We continue to work with stakeholders to identify shorter-term solutions to the ^{99}Mo supply for SNM members and their patients. Although no obvious solution is in sight, we are assisting those who are working on this problem by communicating with regulators and others about the need for rapid implementation of new processes and capabilities.

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