

- Encourage the implementation of quantitative and semi-quantitative methodologies that can support standardization efforts; such efforts might also be used to further encourage and validate cross-vendor comparability of instrumentation, which remains a major challenge to collaborative research across institutional and geographic boundaries.
- Create and sustain partnerships and collaborations that can serve to advance molecular imaging by involving multiple communities and viewpoints. Suggested partners included the National Institutes of Health, the National Institute of Standards and Technology, the U.S. Food and Drug Administration, the Centers for Medicare & Medicaid Services, the American College of Radiology Imaging Network, the American Society for Therapeutic Radiology and Oncology, the American Society of Clinical Oncology, the American Association for Cancer Research, the American Heart Association, the American Society of Nuclear Cardiology, the American Academy of Neurology, the Academy of Molecular Imaging, the Society for Molecular Imaging, the International Society for Optical Engineering, the American Association of Physicists in Medicine, the Institute of Electrical and Electronics Engineers, and manufacturers of devices, radiopharmaceuticals, and software.

To prepare to meet the challenges in training and education, the group recommended action to:

- Encourage the SNM to build on the current strengths in molecular imaging education at its annual and midwinter meetings and to encourage the participation of other molecular imaging specialists.
- Develop a needs assessment program for graduate education to enrich the proposed 3-year nuclear residency as well as the diagnostic radiology residency.
- Encourage the addition of components to these graduate curricula that would allow the incorporation of

instruction on new molecular imaging modalities on an ongoing basis.

- Encourage collaborative and cooperative discussion of the effects of rapid evolution in the field, particularly in the area of cross-specialty training.
- Consider the establishment of centers of excellence for molecular imaging training for physicians, scientists, chemists, physicists, and clinical trial specialists. (Participants noted that recent cuts in U.S. Department of Energy funding are likely to have significant adverse effects on the few such centers that currently exist.)
- Encourage intensive and diversified educational efforts about molecular imaging targeted at referring specialists; residents, fellows, and practitioners in other imaging fields; technologists; technicians engaged in basic research; patients and patient advocates; industry; and federal and nonfederal sponsors.

### Summary Statement

Rapid development in a field with multiple potential applications in research and in clinical benefits demands the creation of a durable infrastructure that rests on reliable standards and on a continuous supply of well-trained and dedicated scientists. Molecular imaging, which is among the fastest growing fields in modern medicine, will need substantial investment from its constituent communities to see that such an infrastructure is put in place and nurtured. SNM is in a position to partner with other organizations to initiate this process and to work to provide the continuous updates and innovation that must accompany accelerated change and growth.

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## PRESENTATIONS

# PET Standardization, NIH Findings: The Importance of Standardization of Imaging in Clinical Trials

**I**maging plays an integral role in current clinical trials. The gamut of imaging modalities available for clinical trials ranges from anatomic imaging—evaluating bidimensional and volumetric data—to molecular and functional imaging—assessing metabolism, vascularity, oxygenation status, receptor status, etc.

At the National Cancer Institute (NCI), we have been particularly interested in advancing the role played by imaging in both the diagnosis and management of the cancer patient (*1*). In addition, tremendous interest is focused on advancing the role of imaging in the field of drug development, and increased emphasis is put on therapeutic

clinical trials that use measures of metabolic change to assess therapeutic response rather than conventional CT or MR imaging measurements of change in tumor size. PET assessment of changes in tumor uptake of  $^{18}\text{F}$ -FDG has been gaining acceptance as one such measure.

$^{18}\text{F}$ -FDG PET has now become a commonly used imaging modality in oncology, primarily because of the widespread availability of PET instruments, an accumulation of clinical data, and the gradual expansion of oncology indications for which Medicare will reimburse providers. With this increasing clinical experience, it is becoming clear that  $^{18}\text{F}$ -FDG PET may have an important role as both an effective clinical management tool and as a surrogate endpoint for assessing the clinical efficacy of novel oncologic therapies. Although  $^{18}\text{F}$ -FDG PET is increasingly used as a biomarker for predicting therapeutic response, we lack widely accepted and standardized protocols for using  $^{18}\text{F}$ -FDG PET as a tool for assessing response to therapy.

### The Development of Consensus Guidelines

It is increasingly clear that the potential of  $^{18}\text{F}$ -FDG PET as such a tool will not be achieved unless standard protocols are developed to facilitate the accumulation and comparison of data across multiple clinical sites. A review of scientific publications indicates that the methods currently used to acquire  $^{18}\text{F}$ -FDG PET images and to assess FDG metabolism and tracer uptake are varied.

To provide such guidance and to help standardize the acquisition and interpretation of  $^{18}\text{F}$ -FDG PET in clinical trials sponsored by NCI, the Cancer Imaging Program (CIP) of the NCI convened a workshop in 2005 in Washington, DC, to review the status of  $^{18}\text{F}$ -FDG PET technology and clinical experience in both diagnosis and monitoring response to therapeutic interventions. The assembled group of experts focused their review and recommendations on patient preparation, image acquisition, image reconstruction, quantitative and semiquantitative analysis of  $^{18}\text{F}$ -FDG PET images, quality assurance issues, reproducibility, and other parameters of importance to be used in PET studies before and after a therapeutic intervention. Their discussions were based on a review of the existing medical literature as well as on the expertise of those participating in the working group.

The workshop formed the basis for the development of guidelines that were honed over a series of discussions in

the working groups over the next several months. These consensus recommendations were published in *The Journal of Nuclear Medicine* (1). It is the NCI's intention that these guidelines will serve as the recommended set of procedures for the performance (i.e., acquisition and analysis) of  $^{18}\text{F}$ -FDG PET imaging of patients participating in NCI-sponsored diagnostic and therapeutic clinical trials.

In addition, the CIP has also engaged the MR imaging community in a similar process to develop consensus guidelines for the performance of dynamic, contrast-enhanced MR imaging as well as MR spectroscopy. These guidelines and additional information are available at the CIP Web site (<http://imaging.cancer.gov/>).

Among the questions that merit additional discussion are:

- (1) What is the appropriate process for implementation of the guidelines in NCI trials?
- (2) How will/should these guidelines be accepted and incorporated into other cancer trials?
- (3) How will data coming out of these trials be evaluated?
- (4) What constitutes a critical mass of trial data for defining test characteristics (i.e., variability, precision, accuracy, etc.)?
- (5) How will criteria/guidelines be developed for defining relevant clinical parameters (i.e., stratifying patients to higher or lower risk, defining partial or complete therapy response, etc.)?
- (6) How will the guidelines for acquisition, analysis, and interpretation be kept current and accurate in the face of constant change in the pertinent technologies and therapeutics?

### REFERENCE

1. Shankar LK, Hoffman JM, Bacharach S, et al. Consensus recommendations for the use of  $^{18}\text{F}$ -FDG PET as an indicator of therapeutic response in patients in National Cancer Institute trials. *J Nucl Med*. 2006;47:1059-1066.

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## Education and Training Activities at the NIBIB

**T**he National Institute of Biomedical Imaging and Bioengineering (NIBIB) supports training directly by providing individual and institutional training grants

and indirectly by providing research grants. More than 180 individuals are supported at the predoctoral or postdoctoral level through individual and institutional training grants.