

Amyloid Imaging Progress at FDA

A recent meeting convened by the U.S. Food and Drug Administration (FDA) provides optimism for the introduction of new molecular imaging agents for clinical use, particularly for imaging amyloid in the brain.

The FDA was approached by several companies for advice about the design of phase 3 clinical studies of radiopharmaceuticals to detect cerebral amyloid. It convened a meeting of its Peripheral and Central Nervous System Drugs Advisory Committee on October 23, 2008. The committee was augmented by SNM members Henry Royal, MD; Harvey Zeissman, MD; and Peter Herscovitch, MD. Presentations on ^{18}F -labeled radiopharmaceuticals for amyloid imaging were made by Avid Radiopharmaceuticals, Inc.; Bayer Healthcare Pharmaceuticals, Inc.; and GE Healthcare.

The advisory committee was asked to consider 3 topics. The first was to what extent would a radiopharmaceutical to detect cerebral amyloid provide useful clinical information. The second question was that if such a radiopharmaceutical were clinically useful, what should be the “standard of truth” against which its performance should be compared in phase 3 studies. The third was to comment on the proposed study designs.

The committee agreed that a PET scan showing absent brain amyloid could provide clinically useful information in ruling out a diagnosis of Alzheimer’s disease. The members believed that a positive test would have limited utility because amyloid can be present in other conditions. The committee also believed that an amyloid imaging agent could

be valuable for clinical research—for example, in the development of anti-amyloid therapies.

Extensive discussion addressed the “standard of truth” for the proposed phase 3 clinical studies. The committee overwhelmingly agreed that it should be histopathologic confirmation of amyloid in autopsy studies in individuals who had undergone an antemortem scan, although such studies might be difficult to arrange. It was agreed that a clinical diagnosis of Alzheimer’s disease, even if made by a specialized team using research criteria, was not an appropriate “gold standard” for the presence of brain amyloid.

It is noteworthy that the committee was asked to consider an indication relating to the detection of a pathological process, not a disease-specific indication to diagnose Alzheimer’s. Several other PET radiopharmaceuticals may have indications based on their biochemical or pathological imaging characteristics (e.g., agents to image tissue hypoxia, cellular proliferation, and angiogenesis). Therefore, this meeting had broader implications by providing a model for a process by which other molecular imaging agents could receive approval for clinical use.



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MAINTENANCE OF CERTIFICATION

MOC Featured at SNM Annual Meeting

Requirements for Maintenance of Certification (MOC) Part II (self-assessment) and Part IV (practice-based assessment and improvement) will be a focus at SNM’s Annual Meeting, to be held in Toronto, June 14–17. The SNM Arena will include an MOC booth this year. In addition to materials and demonstrations of SNM’s Lifelong Learning and Self-Assessment Program, information will be available about SNM’s new Practice Performance Assessment Program, which is designed to assist physicians participating in MOC with meeting Part IV requirements. In addition, members of the American Board of Nuclear Medicine will be on hand at the MOC booth to answer diplomates’ questions concerning MOC. The Annual Meeting Program Book includes the schedule.

This year SNM will offer 11 self-assessment module (SAM) credits. A session titled “MOC: Practice Performance Assessment” will be among the sessions offering

SAM credits, enabling attendees to earn needed credits while learning more about MOC. Other SAM session topics include: Best Practices in PET/CT, Diagnostic Challenges in FDG PET/CT Interpretation, Dementia—PET/SPECT, and PET/CT Optimal Interpretation and Reporting in Hybrid Cardiac Studies. The Online Meeting Planner (<http://www.snm.org/index.cfm?PageID=8362>) features more information about the SAM sessions.

The SNM 2009 Annual Meeting offers the opportunity to catch up on SAM credits and learn more about MOC Part IV requirements.



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