

Imaging Biomarkers Roundtable Report

Interest in using imaging techniques as biomarkers for primary or secondary endpoints in clinical trials is increasing, especially for therapeutic drug trials. Testing molecular imaging techniques as biomarkers that can predict response to therapy is of particular interest.

A variety of academic, commercial, and government groups are addressing one or more aspects of the evaluation and validation of imaging methods as biomarkers in clinical research, and communication among these groups is often minimal or nonexistent. To promote an exchange of information, assist all of these individual groups in sharpening the focus of their own goals and missions, and reduce duplication of effort, the Radiological Society of North America convened an Imaging Biomarkers Roundtable in Oak Brook, IL, on April 3 and 4. Twenty-two groups, including 2 European groups, reported on their current and planned activities. A list of important unsolved problems or areas requiring increased attention—such as the need for

improved phantoms, standardized image acquisition protocols, approved lexicons, publicly available image archives, reduced regulatory hurdles, and increased funding for validation trials—was compiled. A matrix listing all the various groups and their particular activities in evaluating or validating imaging biomarkers is being developed based on information shared at the roundtable, and a roadmap or blueprint showing the more complex interrelationships among these various groups and projected timelines of their activities will follow.

Based on discussions at the Roundtable, increased emphasis will be placed on developing a library of standardized protocols for use in clinical trials and on working



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MAINTENANCE OF CERTIFICATION

Maintenance of Licensure and Maintenance of Certification

Each state is responsible for licensing physicians, and each state medical board has its own rules and regulations. The Federation of State Medical Boards (FSMB) is the umbrella organization that helps to standardize the process. On May 3, the FSMB House of Delegates took the next steps in developing a model policy for maintenance of licensure (MOL). This policy will assist states in requiring physicians to demonstrate their continuing competence as a condition of relicensure (www.fsmb.org/m_mol.html). The draft model policy requires physicians to take part in ongoing self-assessment and to demonstrate continuing competence in their areas of practice.

The FSMB House of Delegates also approved 5 guiding principles for policy development:

- MOL should support physicians' commitment to lifelong learning and facilitate improvement in physician practice.

- MOL systems should be administratively feasible and should be developed in collaboration with other stakeholders. The authority for establishing MOL requirements should remain within the purview of state medical boards.
- MOL should not be overly burdensome for the profession and should not hinder physician mobility.
- The infrastructure to support physician compliance with MOL requirements must be flexible and offer a choice of options for meeting requirements.
- MOL processes should balance transparency with privacy protections.



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None of these challenges will be solved in a single year. There has been a concerted effort to develop a comprehensive strategy among the leadership of SNM to ensure a continuity of approach beyond any individual's presidency. Immediate Past-President Alexander McEwan, MD, has worked hard to develop a consensus with President-Elect Michael Graham, PhD, MD, and me, and with SNM's immediate Past-President David

Gilmore and President Mark Wallenmeyer, so that many of these initiatives will continue. I have pledged to continue this collaborative approach. Our commitment is vital to the health and welfare of our field, those who work in it, and those we treat.

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SNM President*

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with the major manufacturers of medical imaging devices to improve the accuracy and reproducibility of quantitative results associated with imaging methods.

The imaging device manufacturers will come together under a new initiative called the Quantitative Imaging Biomarkers Alliance to identify specific problems they can solve in pursuit of our mutual goal: more accurate and reproducible quantitative results. Creating and providing public access to large datasets of images and associated clinical outcome

data is another important task which, so far, has been difficult to accomplish and needs more concerted attention. Many attendees used the term "eye opener" to describe the meeting, and participants requested future opportunities for continued communication and coordination of activities.

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Most physicians currently demonstrate their competence to their licensing boards only once—when they first apply for a license to practice medicine. When state medical boards implement MOL requirements, physicians will be expected to demonstrate their competence periodically in order to maintain active medical licenses.

The American Board of Nuclear Medicine (ABNM) expects that its maintenance of certification (MOC) require-

ments will satisfy the MOL requirements of the state medical boards. The ABNM will do everything it can to make sure that diplomates participating in MOC will be required only to document their participation in MOC in order to maintain their licensure.

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