

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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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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