A Collaborative Enterprise for Multi-Stakeholder Participation in the Advancement of Quantitative Imaging[1]

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For the Group

Medical imaging has seen substantial and rapid technical advances during the past decade, including advances in image acquisition devices, processing and analysis software, and agents to enhance specificity. Traditionally, medical imaging has defined anatomy, but increasingly newer, more advanced, imaging technologies provide biochemical and physiologic information based on both static and dynamic modalities. These advanced technologies are important not only for detecting disease but for characterizing and assessing change of disease with time or therapy. Because of the rapidity of these advances, research to determine the utility of quantitative imaging in either clinical research or clinical practice has not had time to mature. Methods to appropriately develop, assess, regulate, and reimburse must be established for these advanced technologies. Efficient and methodical processes that meet the needs of stakeholders in the biomedical research community, therapeutics developers, and health care delivery enterprises will ultimately benefit individual patients. To help address this, the authors formed a collaborative program—the Quantitative Imaging Biomarker Alliance. This program draws from the very successful precedent set by the Integrating the Healthcare Enterprise effort but is adapted to the needs of imaging science. Strategic guidance supporting the development, qualification, and deployment of quantitative imaging biomarkers will lead to improved standardization of imaging tests, proof of imaging test performance, and greater use of imaging to predict the biologic behavior of tissue and monitor therapy response. These, in turn, confer value to corporate stakeholders, providing incentives to bring new and innovative products to market.

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Radiology

Enhanced imaging techniques have made medical imaging an essential component of most episodes of care. Imaging is especially valuable because it provides spatially and temporally localized anatomic and functional information with use of noninvasive or minimally invasive methods. Until now, clinical radiology has comprised radiologist review of images acquired under a variety of conditions but interpreted essentially the same way, which is for the reader to visually evaluate the image, possibly with use of screen tools such as calipers for the measurement of line lengths. However, an increasing number of approaches to quantitative analysis have been pursued that create objective and quantitative readouts that range from morphologic to functional measurements. Some of these methods use single images and others use dynamic sequences that enable the assessment of time-dependent behavior. In general, however, they involve numeric computation with use of a large amount of the available data from the image to provide a measure that is more closely related to the underlying biologic characteristics than may be easily appreciated by the human eye. These capabilities are used in preclinical studies, in translational medicine, and, increasingly, in the clinic.

Advances in Knowledge

- Understand how quantitative techniques increase the utility and value of imaging.
- Understand what unique problems and challenges are posed by quantitative imaging.
- Identify the reasons why a collaborative approach is needed by the community.
- Describe how the Integrating the Healthcare Enterprise methodology may be applied to a collaborative approach in the imaging sciences.
- Explain how the Quantitative Imaging Biomarker Alliance (QIBA) has been formed and how it is engaging stakeholders to fill key needs to promote the wide availability of quantitative imaging.

Potential Conflicts of Interest

Individual company interests are not addressed, but the health of the industry and the effectiveness of working relationships are to the advantage of all stakeholders. B.B. works for Siemens Healthcare; whereas there is no direct financial interest related to Siemens alone, there is industry-wide interest. M.L.G. is a stockholder in R2 Technology/Hologic and receives royalties from Hologic, GE Medical Systems, MEDIAN Technologies, Riverain Medical, Mitsubishi, and Toshiba. It is the University of Chicago conflict of interest policy that investigators disclose publicly actual or potential significant financial interest that would reasonably appear to be directly and significantly affected by the research activities. S.G. is an employee of GE Global Research. G.M. is a founder and part owner of a lung image analysis software company, VIDA Diagnostics. C.G.M. is employed by BioClinica, a commercial imaging core laboratory that conducts assessments of radiologic images. K.O. has no direct financial interest in the subject matter discussed in this article; however, he has indirect interest because the quantitative imaging discussed herein involves the use of imaging systems and his employer, among other companies, manufactures and sells such systems. B.A.S. is a stockholder and on the Medical Advisory Board of Radiology Corporation of America and is on the Senior Scientific Advisory Board of Siemens Molecular Imaging. A.G.S. receives research support from and is a consultant to pharmaceutical companies using imaging to monitor treatment effects and magnetic resonance imager manufacturers. Details are available at *www.biomarkers.org*.

Implications for Patient Care

- Quantitative imaging helps the delivery of care to be more objectively verifiable and consistent.
- Quantitative imaging enables new models that both contribute to more efficient drug development and allow more individualized treatments.
- The cross-stakeholder activity being pursued by QIBA should make quantitative imaging more widely available to a greater patient population.

Advantages of Quantitative Imaging

Quantitative imaging has the potential to improve the value of diagnostic testing and enhance clinical productivity and is increasingly important to preclinical studies, clinical research, and clinical practice (1–5).

Clinical trials have been at the forefront of the drive to incorporate quantitation into practice in imaging technologies. In the early phases of clinical testing of novel therapeutic agents, quantitative imaging contributes to the understanding of underlying biologic pathways and pharmacologic effects. It may also provide needed data that may reduce the cost and time necessary to develop

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Abbreviations:
FDA = Food and Drug Administration
IHE = Integrating the Healthcare Enterprise
QIBA = Quantitative Imaging Biomarker Alliance
QIN = Quantitative Imaging Network
RSNA = Radiological Society of North America
UPICT = Uniform Protocols in Clinical Trials

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Guarantors of integrity of entire study, A.J.B., G.S.D.; study concepts/study design or data acquisition or data analysis/interpretation, all authors; manuscript drafting or manuscript revision for important intellectual content, all authors; approval of final version of submitted manuscript, all authors; literature research, A.J.B., H.J.W.L.A., B.B., R.B., P.E.C., P.S.D., N.R.D., W.E., C.E., D.G., S.N.G., E.F.J., P.E.K., G.M., P.D.M., L.H.S., A.G.S., R.L.W., J.C.W., G.Z., D.C.S.; clinical studies, H.J.W.L.A., P.S.D., P.D.M., L.H.S., A.G.S.; statistical analysis, H.J.W.L.A., C.G., D.R.; and manuscript editing, A.J.B., H.J.W.L.A., B.B., R.B., J.M.B., L.B., D.B., P.E.C., J.J.C., G.S.D., P.S.D., N.R.D., W.E., C.E., R.A.F., M.L.G., D.G., S.N.G., E.F.J., L.K., G.J.K., P.E.K., G.M., C.G.M., P.D.M., K.O., R.P., D.R., M.R., H.R., L.H.S., B.A.S., A.G.S., R.L.W., J.C.W., W.W., G.Z., B.Z., D.C.S.

Figure 1

Figure 1: Diagram illustrates uses of quantitative imaging in the drug development pipeline. Applications of quantitative imaging in therapy development stem from the ability to enable adaptive clinical trial designs by providing more sensitive measures, the ability to predict responders from nonresponders on the basis of characteristic imaging phenotypes, the contribution to evidence allowing unpromising programs to be terminated earlier in their life cycle versus that which is possible without the information, the ability to optimize dose level and schedule by evaluating response, and contributions to rationale-based combinations.

Figure 2

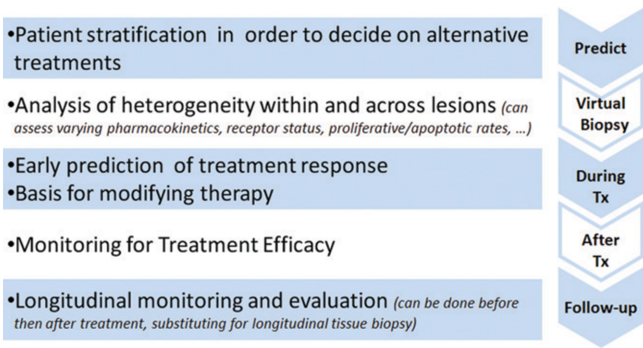

Figure 2: Diagram shows how quantitative imaging can be used to help diagnose and monitor disease. Applications of quantitative imaging in individual patient treatment (*Tx*) range from predicting the onset of disease symptoms before they are experienced (by means of highly resolved diagnoses capable of being repeated in time and the differentiation of regional variations) to the selection, modification, and monitoring of therapy (owing to its ability to help stratify patients by phenotype on the basis of imaging characteristics) and the quantification of treatment effects longitudinally.

novel pharmaceutical and therapeutic agents (6). In later phases of development, imaging biomarkers may serve as important end points for clinical benefit (7,8). In all phases of drug development, imaging biomarkers may be used to select or stratify patients on the basis of disease status so as to better demonstrate therapeutic effect (Fig 1). Although imaging biomarkers need not be quantitative, quantitation provides a means for comparison across centers and can help obtain objective measures of the underlying biologic characteristics that are less subject to reader differences.

Improved patient selection with use of quantitative imaging could reduce the required sample size for a given trial and help identify the subpopulation that could benefit most from the proposed treatment. This should reduce the development time and cost of new drugs and might also result in a reduction in the size of the "target" population accordingly. In addition, it might also advantageously reduce unnecessary exposure and the resulting adverse effects, thus improving the overall risk-to-benefit ratio of a new drug. To be practically useful, however, the imaging metrics must be quantitative such that absolute levels of indexes are known and can be reported across sites and trials.

In addition, quantitative imaging is increasingly being used in the treatment of individual patients for diagnosing and monitoring disease, as shown in Figure 2 (an example from the oncology community).

Problems Related to Quantitative Imaging

The imaging industry is transitioning to the development of devices that are optimized for quantitative imaging. Paradoxically, however, the regulatory clearance and approval of new imaging devices, software, and agents has been slowing in the past decade (9–13). Slow regulatory clearance and approval limits the availability of these methods to realize the advantages of quantitative imaging to drug development in addition to applications in individual patient treatment.

This slowing largely derives from an increasing regulatory expectation that the performance characteristics of imaging tests be more rigorously defined than was previously the case. The prospective collection of imaging data in multisite trials is essential for validating and qualifying imaging biomarkers, which is required for advancing their use (14). Not only are the data from prospective studies of imaging methods crucial, but observation of how well the imaging is performed "in the field" will help determine what steps are needed to make imaging biomarkers clinically practical. Success will be achieved when quantitative imaging biomarkers are widely disseminated and not simply available in prospectively selected, controlled imaging environments.

Performance expectations, and particularly the rigor with which performance is statistically characterized, are higher with quantitative imaging than with qualitative imaging, drawing an analogy to in vitro laboratory assays (15). However, quantitative imaging has a number of roadblocks: Manufacturers have proprietary protocols, the field moves quickly and, therefore, stable products are difficult to implement, and the costs and time necessary to overcome these roadblocks and meet the performance expectations are often out of reach of single entities owing to cost and/or organizational issues.

Need for a Collaborative Approach

Efforts by individual manufacturers to establish quantitative imaging parameters as biomarkers are often more costly and time-consuming than the efforts needed for traditional device clearance or approval. This is because qualification requires data from clinical trials to demonstrate that the imaging biomarker of interest correlates with a meaningful clinical end point. Individual companies are constrained by their business model to pursue only activities that can be justified in the short term with respect to that company alone. Furthermore, individual manufacturers do not commonly address the need for cross-vendor standardization, which would enable a level of clinical effectiveness not currently possible when a given quantitative parameter depends in part on nonbiologic factors such as vendor differences. Therefore, a cooperative structure is necessary to obtain the standardization needed to minimize variation in multicenter studies and allow comparison of results from different trials. With such standardization in place, it would be possible to perform multiple studies and pursue objectives that would not be feasible for individual sponsors of clinical research alone, be they biopharmaceutical companies seeking to develop drugs or hardware and/or software companies seeking to develop solutions for clinical care. Although many stakeholders are interested in this goal, none can accomplish it alone.

Stakeholders with an interest in advanced imaging agree that there is an increasing lag between the development and commercialization of many seemingly compelling imaging techniques. This is a disincentive to continued investment at a time when the market very much needs these tools. Because the return on investment for the manufacturer is dependent on clinical sales, the incentive to invest in the development of new imaging products (eg, advanced imaging techniques that require contrast agents and/or software) is diminished by slow regulatory approval (16). The future development and implementation of quantitative imaging relies on coordination among manufacturers, regulatory organizations, health care providers, academic institutions, groups using imaging in clinical trials (which will be the first to try innovative methods), biopharmaceutical companies, imaging contract research organizations, professional societies, and practicing physicians. Patients and the entire health care industry will benefit from an even more appropriate use of imaging, which will be supported by validation, qualification, standardization, and comparative effectiveness research. Although manufacturers must remain attuned to development cost and time to market, every stakeholder will benefit from technologic, commercial, and utilization advances in imaging biomarkers.

The National Cancer Institute has recently initiated the Quantitative Imaging Network (QIN) to evaluate imaging methods with which to measure the response to cancer therapy (17). The goal of the QIN is to create multidisciplinary teams of oncologists, radiologists, medical physicists, and computer and informatics scientists who will work with industry partners to develop as a public resource both retrospective and prospective databases with clinical outcome data. The clinical data are to be acquired from both national and international clinical trials. The intent is to develop, optimize, and validate current and emerging quantitative imaging and image-processing methods for measuring the response to drug and radiation therapy. The scope includes a full array of commercial imaging platforms for different targeted organ systems. The QIN will use a recently extended resource, the Reference Image Database to Evaluate Response project (18–23), as well as recent consensus-based publications addressing quantitative imaging measurement uncertainty with use of phantoms and human subjects. An important goal of the QIN is to extend these public resources to allow academic and industry scientists to compare results from current and emerging quantitative imaging methods.

The Quantitative Imaging Biomarker Alliance

Origins of the Alliance

Efforts to develop public resources and open source tools for qualifying imaging as a biomarker were reinvigorated in 2005 by an informal alliance between the National Cancer Institute, the National Institute of Biomedical Imaging and Bioengineering, the National Institute of Standards and Technology, and the U.S. Food and Drug Administration (FDA) (24–27). Preliminary work led to the organization of an interfederal agency–sponsored public workshop held at National Institute of Standards and Technology headquarters in September 2006 (28). This workshop addressed the physical standards that would be required for qualifying medical imaging techniques as biomarkers. Stakeholders from academia, industry, regulatory agencies, patient advocacy groups, and scientific imaging societies participated in the workshop. A model similar to the Integrating the Healthcare Enterprise (IHE) initiative was endorsed as a means to organize and encourage collaboration among diverse stakeholders. An alliance of this sort was thought to be necessary because the development of new or enhanced imaging technologies can be complex and expensive. (See Appendix E1 [online] for a discussion of the IHE process.)

In November 2006, the Radiological Society of North America (RSNA) convened a group of stakeholders to advise it on what role it could most constructively play with regard to imaging biomarkers. The RSNA subsequently developed, and continues to sponsor, multiple initiatives to promote the objective extraction of quantitative information from clinical images (29). It sees this approach as the appropriate one to stimulate the necessary groundwork to support use of imaging as a biomarker (30,31). The initial focus has been on imaging in clinical trials, with the intent to generalize to imaging in clinical care.

The goal is to establish stakeholder collaboration to gain acceptance by the imaging community and regulatory agencies of quantitative imaging biomarkers as proof of biologic processes (including treatment-induced pathophysiologic changes) that act as biomarkers for changes in the health status of patients.

The Quantitative Imaging Biomarkers Alliance (QIBA) arose from a public session at the 2007 annual RSNA meeting. It first met as a group in May 2008.

Purpose of QIBA

The coordinated activities of QIBA provide a mechanism by which the best collective thinking of stakeholders works together to *(a)* articulate requirements, *(b)* characterize and optimize system performance, and *(c)* collect evidence.

QIBA seeks to create a shared result that passes muster for regulatory agencies and decision making about reimbursement.

QIBA engages the major equipment manufacturers in the process of improving the accuracy and precision of measurements that come from their imagers. QIBA's mission is to "[i]mprove the value and practicality of quantitative imaging biomarkers by reducing variability across devices, patients, and time," that is, to reduce variability due to nonbiologic factors such that the measurements may be understood to reflect true biologic differences rather than technical artifacts.

On the basis of the RSNA IHE initiative, QIBA set out to apply the IHE process in the context of quantitative imaging rather than ensuring interoperability. The IHE focuses on engineering problems for which the scientific problems have largely been solved (ie, in data exchange between systems). QIBA, conversely, identifies and refines key scientific precursor questions and concepts needing validation and then coordinates the research and other groundwork to answer the scientific questions and establish profile definitions.

A profile is a document that includes claims and details. The claims tell a user what can be accomplished by following the profile. The details tell a vendor what must be implemented in their product before they can declare compliance with the profile. The details may also define related user procedures necessary for the claims to be achieved. QIBA Technical Committees are resolving groundwork issues and developing quantitative imaging profiles. Profiles are developed by means of a four-step process that leads to the development and adoption of quantitative imaging biomarkers. The first step is to identify sources of error and variation in quantitative results from imaging methods. Then, potential solutions are specified. Stakeholders identify potential strategies and infrastructure for error mitigation and collaborate on the development of hardware, software, and protocol solutions, documenting them in the form of QIBA profiles. The third step is to test solutions. Vendors and researchers implement QIBA solutions to assess their feasibility and efficacy. The last step is the promulgation of solutions. Validated solutions are disseminated and implemented by means of vendor adoption, research integration, and clinical education.

Related Activities

The Imaging Biomarker Roundtable brings together any group active in some aspect of imaging biomarker evaluation to explore the collective potential for and interest in coordination, communication, and high-level strategic planning. During the past 2 years, the Imaging Biomarker Roundtable has convened regular working groups to determine actions needed for specific imaging biomarkers and proposed an organizational context that has the potential to move the industry forward.

The Uniform Protocols in Clinical Trials (UPICT) group facilitates access to and deployment of widely accepted, consistent imaging protocols (including imaging quality control procedures) for use in clinical trials across a range of disease states, anatomic sites, geographic sites, and imaging modalities. The UPICT group has generated a template for multicenter imaging protocols and entered existing protocols from research groups with widely accepted credibility. The UPICT group promotes a standardized format so that protocol presentation is parallel across imaging modalities and techniques. This standardization allows comparison across protocols and progress toward consensus. Ultimately, the UPICT group seeks to increase efficiency in the execution of clinical trials by facilitating common approaches and compatible data formats.

The Toward Quantitative Imaging initiative seeks to educate the imaging community and user groups about quantitative imaging (32). One aspect of that educational process is to increase awareness of the clinical value of quantitative results from imaging tests, thus creating customer demand for imagers that are "measuring" instruments rather than just imaging devices.

The Clinical and Translational Science Awards Imaging Working Group seeks to take advantage of the National Institutes of Health–funded Clinical and Translational Science Awards Consortium to improve the infrastructure for translational research in imaging departments and the utilization of that infrastructure by translational scientists from academia and industry. The RSNA has an agreement and works with the National Center for Research Resources to sponsor and facilitate the Clinical and Translational Science Awards Imaging Working Group efforts.

The QIN of the National Cancer Institute complements the goals of QIBA. The administrative oversight of the QIN is exercised under a steering committee and an external advisory committee, with planned representation from the FDA and National Institute of Standards and Technology (6) as well as scientific coalitions such as the QIBA. This research strategy will provide a basis for promoting imaging standards for biomarkers by society and industry stakeholders.

QIBA Going Forward

The intent of the QIBA is to achieve useful standardization across the community (33) and to provide a cost-sharing mechanism (34) to make it more economically feasible to carry out studies on a larger scale. Toward this end, a subset of biomarker development activities has been prioritized for collaborative pursuit (Fig 3).

The QIBA initiative is building momentum, as evidenced by sustained and growing membership. Members believe that QIBA has the potential to efficiently and collectively gather and analyze validation and qualification data on imaging biomarkers useable by regulatory bodies. Working together makes the process more robust than if individual stakeholders were to pursue qualification unilaterally. Once a quantitative imaging biomarker has been accepted by the community, including the national regulatory agencies, it may then be utilized without the need for repeated data collection for new drug applications by pharmaceutical companies and in device clearance or approval applications by imaging device manufacturers. This approach offers stakeholders a cost-effective process for product approval while simultaneously advancing the public health by accelerating the time to market for efficacious drugs, devices, and diagnostic procedures (Fig 4).

Part of the QIBA activity seeks to identify mechanisms to support this proposed construct. An example is the FDA's "device master file" concept (35), whereby multiple applicants may reference a file with the original sponsor's approval. This mechanism could be used to allow the individual sponsors to cite collectively submitted data.

Through QIBA *(a)* the collaborative enterprise acts as a sponsor on behalf of its membership, seeking clearance or approval for a test on a class of devices; *(b)* individual devices are tested for compliance with the class; and *(c)* national regulatory agencies (FDA or foreign equivalents) allow the use of data collected to qualify a quantitative imaging biomarker (across a multiplicity of implementations) to be contributory as evidence for individual device sponsors to use in seeking market approval of individual implementations (thereby accelerating commercialization).

In the end, more consistency can be expected in image interpretation, which should create more efficient multicenter clinical trials and be useful as patients move among providers. QIBA is a joint effort among many societies and industry partners to build a common framework for characterizing and optimizing performance across systems, centers, and time. It will be increasingly possible for physicians to rely on consistent quantitative interpretations as the standard of care. In theory, medical workflows incorporating these stable measures should compare favorably to workflows without them in terms of improved patient outcomes and lower costs of care. Without this effort, variations in measures diminish the value of imaging metrics and restrict their use.

Figure 3

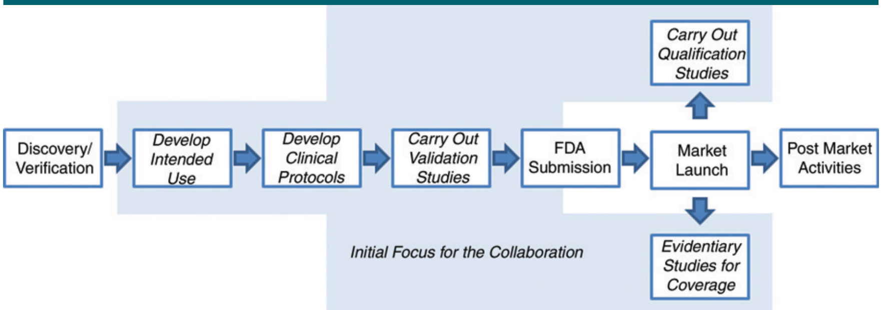

Figure 3: Diagram shows how biomarker development activities have been prioritized for collaborative pursuit. The initial focus for the collaboration is chosen to include those activities after initial discovery and development through actual marketing activities.

Figure 4

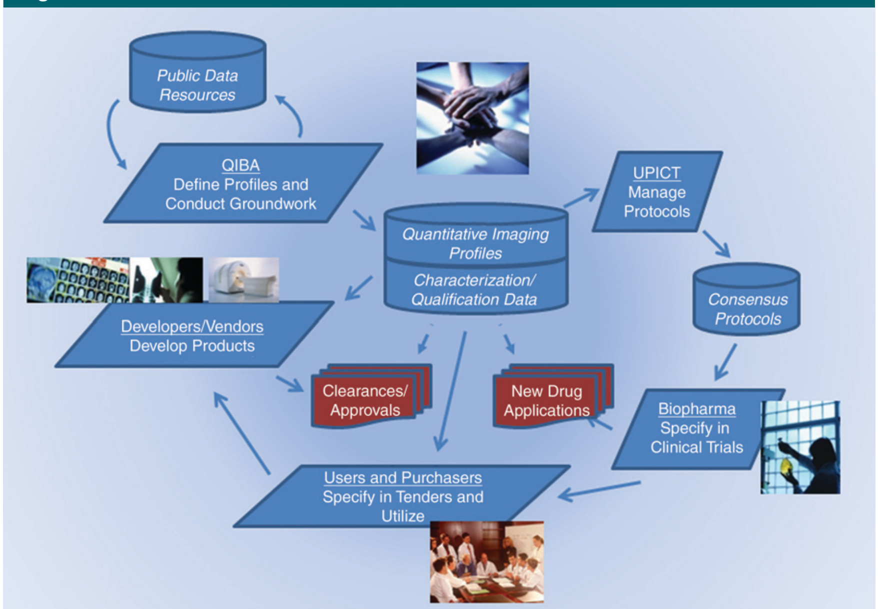

Figure 4: Diagram illustrates QIBA's approach to the development of standards and bodies of evidence to support them to meet various stakeholder needs. Integrated flows across the enterprise represent activity that results in characterization and qualification data with two applications. The first application, the use by biotechnology and pharmaceutical companies in therapeutic clinical trials, is shown on the right. It leads to biomarkers deemed "qualified for use" by national regulatory agencies such as the FDA or foreign equivalents. The second application, which is used by the device industry as shown on the left, creates commercial diagnostic tests approved by regulatory agencies for the "appropriate use" of therapies. In this way, the technical validation data are applicable to both clinical trials and clinical practice, thereby benefitting all stakeholders.

As an organization, QIBA focuses on the development and implementation of standards and processes, such as the profiles discussed earlier, to facilitate the acceptance of imaging not only by the user community but also by regulatory and marketing interests (Fig 5).

By its nature, the collaborative is structured in such a way as to make its resources accessible to a wide user community. Similar to the IHE initiative, QIBA consists of a collaboration of stakeholders, including imaging specialists, device and software manufacturers, biopharmaceutical companies, imaging contract research organizations, regulators, and technical experts, who work together with the ultimate goal of

Figure 5

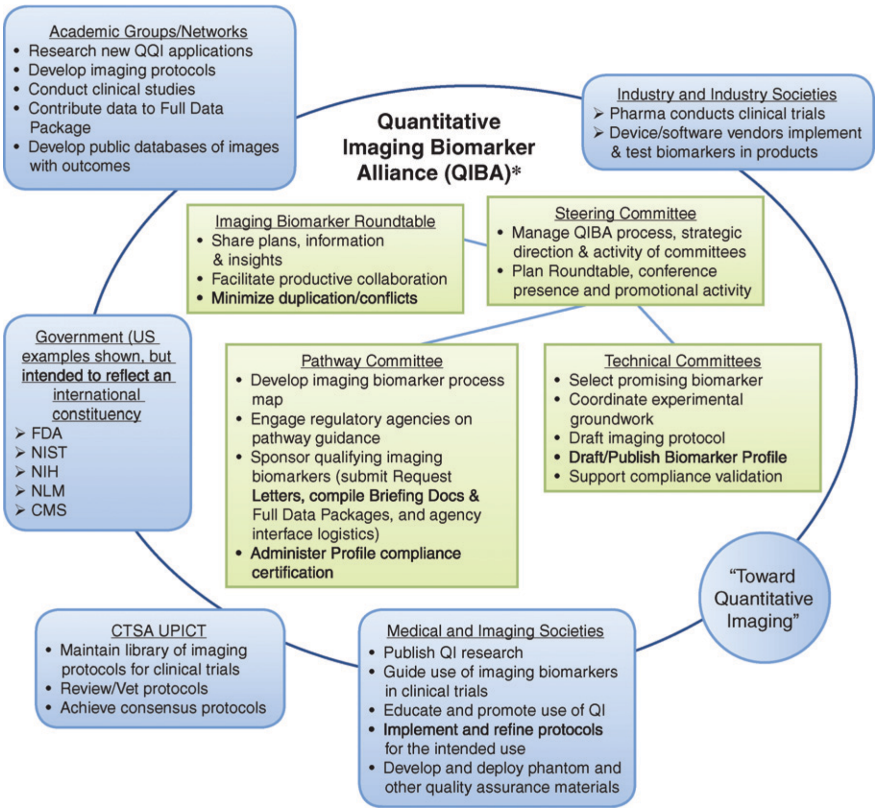

Figure 5: Diagram illustrates how QIBA is organized internally as well as how it relates to external groups. Stakeholders of the QIBA are drawn from each of the constituencies with a role to play in the advancement of quantitative imaging *(QI)* for the benefit of improving patient outcomes, with each having their own unique vantage point. *CMS* = Centers for Medicare and Medicaid Services, *CTSA* = Clinical and Translational Science Awards, *NIH* = National Institutes of Health, *NIST* = National Institute of Standards and Technology, *NLM* = National Library of Medicine, *Pharma* = pharmaceutical companies.

creating a collaborative incubator to leverage technical advancements and expertise toward the quality-assured use of imaging as a biomarker in clinical studies and in diagnostic and therapeutic applications. The organization includes liaisons to industry groups such as the Medical Imaging and Technology Alliance, a division of the National Electrical Manufacturers Association (36), the Pharmaceutical Research and Manufacturers of America (37), imaging societies, the National Cancer Institute (38), and the FDA (39).

Although much of the initial focus has been on clinical trials, the results will benefit the broader applications of quantitative imaging once the results from clinical trials disseminate into clinical practice by means of either eventual expansion of the QIBA's mission or new comparable collaborations.

Summary

To advance the practice of medicine, robust translational research programs must be developed that integrate discovery and clinical application. Imaging has the potential to greatly enhance this process with regard to quantitative imaging biomarkers. As we grapple with the requirements needed to validate and qualify these quantitative imaging biomarkers, we must recognize the incentives needed to attract the necessary spectrum of participants. In addition, incurred expense in resources and time weakens business propositions and, ultimately, the public good; it results in delays at best and an inability to bring valuable innovations to patients at worst.

Business constraints are both real and legitimate. Industry groups have presented arguments on behalf of the supplier community in favor of this collaborative approach, even as individual companies work to preserve their competitive and differentiated products. A collaborative public-private partnership may represent the best approach to moving forward to achieve what we would like to accomplish for society. Even though individual suppliers cannot or do not choose to tackle these problems, the collective enterprise may be able to do it successfully.

We have formed QIBA to enable cooperation and address issues in quantitative medical imaging by adapting the successful IHE precedent to the needs of imaging science.

QIBA both facilitates methodology development and provides an efficient means with which to collectively gather and register validation and qualification data than is generally available to individual sponsors. The approach offers cost-effective product approval processes for industry stakeholders while simultaneously advancing the public health by potentially accelerating the time to market of proved drugs and devices. As such, the collaborative enterprise facilitates the refinement and increased utilization of quantitative imaging. Manufacturers will seek to comply with completed profiles in response to the demand of clinical users for profile-compliant equipment, as has occurred with imaging providers since the American College of Radiology–National Electrical Manufacturers Association Digital Imaging and Communications in Medicine standard was adopted. To improve their overall effectiveness, clinicians will be motivated to require profile-compliant devices on the basis of results of clinical trials that used profile-compliant equipment. Over time, profile-compliant equipment will become the standard of care.

We believe the QIBA approach should be embraced by the global medical community. Following the QIBA process allows all parties to overcome structural, procedural, and financial hurdles. It draws from the very successful precedent set by the IHE effort but is adapted to the needs of imaging science. Strategic guidance supporting the development, qualification, and deployment of quantitative imaging biomarkers will lead to improved standardization of imaging tests, proof of imaging test performance, and greater use of imaging to predict tissue biologic behavior and monitor therapy response. These in turn confer value to corporate stakeholders, providing incentives to bring new and innovative products to market.

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