QIBA Newsletter

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QIBA MISSION
Improve the value and practicality of quantitative imaging biomarkers by reducing variability across devices, patients, and time.

QIBA CONNECTIONS

Quantitative Imaging Biomarkers Alliance (QIBA)

QIBA Wiki

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Comments & suggestions welcome

Daniel C. Sullivan, MD
RSNA Science Advisor

IN MY OPINION

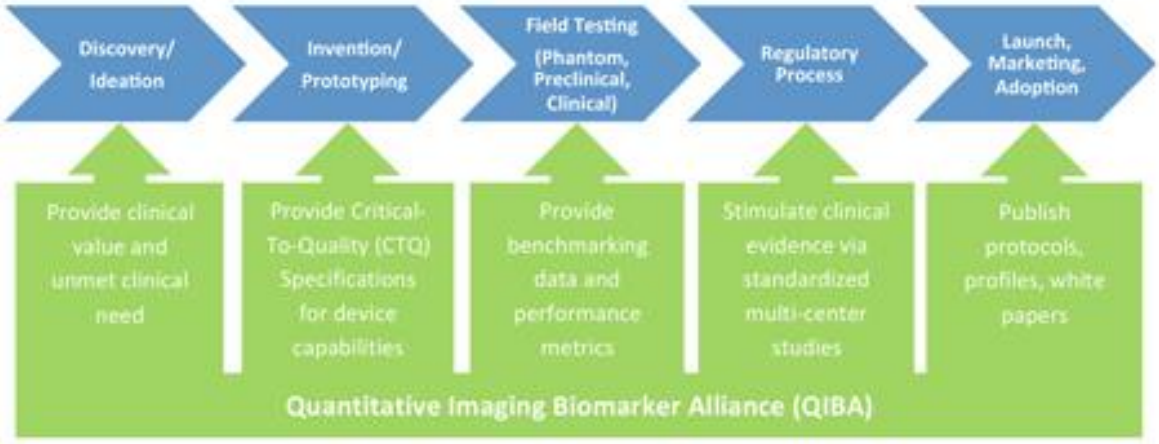
How QIBA Will Benefit Medical Device Innovation

By SANDEEP N. GUPTA, PhD

The Quantitative Imaging Biomarker Alliance (QIBA) is a public-private consortium founded by RSNA with the stated mission of improving the value and practicality of quantitative imaging biomarkers by reducing variability across devices, patients, and time.

QIBA has selected several candidate quantitative imaging biomarkers—Fluorine 18 fluorodeoxyglucose-PET (FDG-PET), CT volumetry, dynamic contrast enhanced MR imaging (DCE-MRI), and functional MR imaging—and has started the groundwork in establishing standards, methods, and processes aimed at accelerating translation of these biomarkers from bench to bedside.

In this article, I make the case that QIBA directly benefits the medical device industry, particularly imaging equipment and medical imaging software manufacturers, and is a catalyst for new and improved device development and innovation. The diagram below illustrates the elements of a typical medical device development pathway (adapted from a U.S. Food and Drug Administration/Center for Devices and Radiological Health white paper on medical device innovation)[1], and the specific ways in which QIBA could impact and facilitate this pathway.



Specifically, QIBA can benefit medical device innovation by:

1. Helping drive the evolution of devices to become more quantitative.
QIBA working groups help establish the clinical value proposition and identify unmet clinical needs which motivate investment by the medical device industry in new, innovative products that improve productivity by being more objective, repeatable, and accurate.

2. Setting quantitative specifications and standards for developing devices.
QIBA technical committees are setting quantitative specifications and standards for acceptable, target, and ideal performance against stated clinical claims and contexts. These specifications directly drive engineering requirements for the device industry that feed into the prototype development pipeline.

3. Providing benchmarking data and helping set performance metrics.
QIBA technical committees, such as the Dynamic Contrast-Enhanced-MR Imaging, (DCE-MRI) Committee, are making available reference data (phantom, simulations, clinical data) which can be used in the device verification and validation process and to assess performance. QIBA is working directly with other consortia and organizations and leveraging existing data repositories where they exist.

4. Facilitating use of quantitative devices and methods in standardized multi-center studies and clinical care by adoption of common protocols and procedures.
QIBA helps speed the regulatory pathway for the device industry by facilitating the use of devices and methods in standardized multi-center trials that help generate clinical evidence and efficacy data required for regulatory submissions. QIBA programs have the potential to lead to the qualification of new quantitative imaging-based biomarkers and their translation into practice. The multi-industry, multi-stakeholder composition of this effort allows companies to benefit from sharing of risk and resources to address this key aspect of device development. By helping establish objective measures of site qualification and compliance of the devices to QIBA recommendations, the sample size and effect size required in clinical studies can be reduced. Beyond regulatory approval, the evidence generated will contribute to establishing efficacy in clinical care.

5. Educating the clinical and research community by publishing profiles, protocols, and white papers.
QIBA can lead to wider adoption and increased use of new quantitative methods by educating the clinical and research community of these new trends. QIBA is doing this by publishing profiles,

protocols, white papers, and educational displays and exhibits, which in turn can drive broader utilization and lead to reimbursement decisions.

Lastly, the QIBA model of shared standards and cooperation by multiple industry representatives in the pre-competitive space is not against the commercial interests of vendors. QIBA helps lay the groundwork for establishing common minimum standards and procedures that drive increased use of these new devices. This does not limit the ability of individual developers to build innovative and differentiated products that offer proprietary features, workflow, user experience, and performance. QIBA is well-positioned to be an essential part of the ecosystem to drive these benefits.

References:

[1] U.S. FDA Medical Device Innovation Initiative White Paper [PDF]

Sandeep N. Gupta, PhD, is the manager of the Biomedical Image Analysis Lab at the GE Global Research Center and a co-chair of the QIBA Dynamic Contrast Enhanced MRI (DCE-MRI) Technical Committee. Dr. Gupta, whose area of expertise is in developing quantitative image analysis algorithms, has contributed to the development of the DCE-MRI profile with emphasis on analysis and quantification methods.

ANALYSIS: TOOLS & TECHNIQUES

Software Development for Analysis of QIBA DCE-MRI Phantom Data

By EDWARD ASHTON, PhD

The ability to ensure that consistent results can be obtained across different imaging sites and scanner types is one of the keys to successful implementation of dynamic contrast enhanced MR imaging (DCE-MRI) in a multisite clinical trial. The most straightforward way to demonstrate that consistent and accurate results are being generated by a particular scanner is through the use of appropriately designed imaging phantoms—test objects with known attributes (geometry, T1 value, etc.) that can be scanned using clinical sequences to test system fidelity. The most important scanner attributes for a DCE-MRI study are the signal-to-noise ratio (SNR) achievable using a T1 weighted dynamic sequence, the accuracy of T1 measurement, and the fidelity of the relationship between changes in T1 and changes in signal intensity.

QIBA has developed a phantom and image acquisition protocol to test these parameters. The goal of this project is to develop a freely distributable software package to allow the quick and convenient analysis of phantom test data. The graphic user interface (GUI) for this package, showing a typical QIBA phantom image, is shown in Figure 1 below:

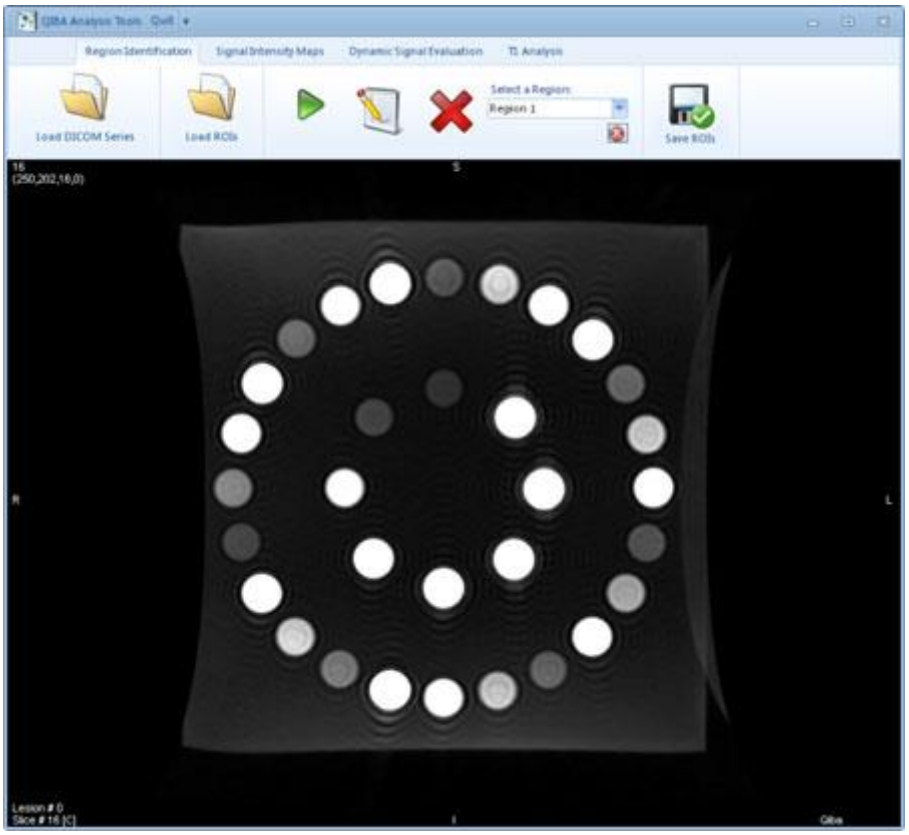


Figure 1: *QIBA phantom analysis GUI displaying QIBA DCE-MRI phantom data.*

The analysis software includes four main tabs:

- **Region Identification**—Methods to load and save image data, to automatically generate consistently ordered regions of interest (ROIs) within the 32 test vials, and to load and save ROI files.
- **Signal Intensity Maps**—Methods to generate maps correcting for signal intensity inhomogeneity resulting from the use of a phased-array receive coil.
- **Dynamic Signal Evaluation**—Methods to automatically calculate band-to-band SNR and ROI-based signal intensity means and standard deviations for dynamic data acquired using the QIBA phantom.
- **T1 Analysis**—Methods to generate T1 maps using any of three possible acquisition techniques: multiple flip angles, multiple inversion recovery time, or multiple repetition time.

Each analysis tab generates a standard report which can be directly imported into a graphing or analysis package such as Microsoft Excel. These reports can then be used to assess the quality of data being generated by a particular scanner and to determine whether that scanner is suitable for use in a DCE-MRI-based clinical trial that incorporates the specifications contained in the QIBA DCE-MRI Profile.

Edward Ashton, PhD, Chief Scientific Officer, is responsible for the scientific and algorithm development for the applications for VirtualScopics. He has extensive custom software development experience in biomedical imaging and military surveillance and reconnaissance. Dr. Ashton is a frequent speaker at international imaging conferences and has authored many peer-reviewed research articles.

FOCUS ON

RSNA 2011: Quantitative Imaging/Imaging Biomarkers and QIBA Meetings and Activities

The Quantitative Imaging Reading Room

RSNA 2011 marked the third year for this educational showcase featuring 21 educational exhibits with visual and experiential exposure to quantitative imaging and biomarkers. These included exhibitor products that integrate quantitative analysis into the image interpretation process at various stages of the workflow process, from image acquisition to structured reporting. Participants learned from exhibits utilizing informational posters, computer-based demonstrations and Meet-the-Expert presentations scheduled throughout the week.

The Special Interest Session, "Quantitative Imaging Biomarkers for Clinical Care and Research," was also well attended.

In addition, QIBA Technical Committees met for a plenary session where RSNA Science Advisor Daniel C. Sullivan, MD, updated the attendees on the QIBA mission, activities, and funded projects, as well as progress on protocols and Profiles. The five QIBA Technical Committees covering quantitative MR, CT, and PET modalities also had an opportunity to work together in breakout sessions on committee-specific projects.

Update on RSNA's 2010 NIBIB Contract for Quantitative Imaging

In 2010, RSNA was awarded a two-year, $2.4 million contract from the National Institute of Biomedical Imaging and Bioengineering (NIBIB) to support RSNA's quantitative imaging and biomarkers programs, specifically, QIBA, formed in 2007 to advance quantitative imaging and the use of imaging biomarkers in clinical trials and practices.

Through the diligent work of its funded investigators and volunteers, this contract supports a coordinated effort to establish an infrastructure for the collection and analysis of imaging biomarker data. The long-term objective is to establish processes and Profiles leading to acceptance by the imaging community, clinical trial industry and regulatory agencies of quantitative imaging biomarkers as proof of biology, changes in pathophysiology and surrogate endpoints for changes in the health status of patients.

Much of the work done by QIBA committees includes groundwork experiments with phantoms and human data that will serve as the foundation for claims to be used in QIBA Profiles. These Profiles will serve as standardized measuring criterion for the future—to evaluate successful medical care—clinical and non-clinical alike.

To date, QIBA has 26 funded projects through the NIBIB contract with a small number of projects pending approval. As there is still much work to be done, further avenues for funding these and future projects are being explored.

This issue's In My Opinion piece, "*How QIBA will Benefit Medical Device Innovation*," by Sandeep N. Gupta, PhD, illustrates how QIBA is already making a difference by increasing the dialogue and buzz about standardization, the benefits of quantitation and how quantitative measurement will ultimately benefit the patient. All of the sub-activities and projects taken on by QIBA volunteers will ultimately benefit patients everywhere.

QI/IMAGING BIOMARKERS IN THE LITERATURE

PubMed Search on: "How QIBA Will Benefit Medical Device Innovation"

Each issue of *QIBA Quarterly* features a link to a dynamic search in PubMed, the National Library of Medicine's interface to its MEDLINE database. Link to articles on: “How QIBA Will Benefit Medical Device Innovation” here.