QIBA Newsletter

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In This Issue:

**US SWS System Dependencies & Phantom Subcommittees are now combined.*

QIBA MISSION

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

QIBA CONNECTIONS

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Contact Us

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NIBIB Funding Support for QIBA Projects

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Chair's Message—The Road to Implementing Quantitative Imaging

The RSNA Strategic Plan strives to advance the radiological sciences and foster the development of new technologies in part by promoting the quantification of imaging results. The added value of quantification in both research and clinical environments is likely to increase as healthcare initiatives place increased pressure on radiologists to provide decision support for evidence-based care.

The demand for quantitative results from imaging studies will increase as treatment decisions are driven by such results. At present there are few clinical situations where that is the case, but there are many clinical scenarios where treating clinicians say they need such information. In order to establish the link between quantitative imaging (QI) results and improved patient outcomes, we need to have reproducible quantitative results from clinical trials. But there remain substantial barriers to reproducible QI measures in clinical trials, including the inherently large number of variables that impede validation of specific metrics, the diversity of proprietary industry platforms, and the lack of acceptance by radiologists.

A critical barrier to the implementation of QI in radiology is the lack of standardization among vendor platforms. Collaboration in the pre-competitive space is challenging yet crucial to address standardization and integrating quantitative measurement into workflows will be necessary for wider adoption. The obstacles to overcome with practicing radiologists include a distrust of the reliability of QI and the fear of diminishing the value of radiologists' expertise through automation and commoditization.

The **Quantitative Imaging Biomarkers Alliance** (QIBA) was officially launched by RSNA in 2007 as a means to unite researchers, healthcare professionals, and industry stakeholders in the advancement of quantitative imaging. QIBA's mission is to improve the value and practicality of quantitative biomarkers by reducing variability across devices, patients and time. This report summarizes our activities, results and future plans. We hope you'll join one of the QIBA committees and help move radiology from being less of an art to more of a science!

~ Daniel C. Sullivan, MD, is the Chair of QIBA and a Professor and Vice-Chair for Research in the Department of Radiology at Duke University Medical Center. Dr. Sullivan also serves as RSNA Science Advisor.

What is QIBA?

A widely-accepted definition of a biomarker is "a characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes or a response to a therapeutic intervention.[1] The term quantitative imaging has recently been defined as "the extraction of quantifiable features from medical images for the assessment of normal or the severity, degree of change, or status of a disease, injury, or chronic condition relative to normal."[2] Combining these two concepts, a quantitative imaging biomarker (QIB) can be conceptualized as an objectively measured characteristic derived from an in-vivo image as an indicator of normal biological processes, pathogenic processes or a response to a therapeutic intervention.

The responsible development of quantitative imaging is a strategic priority for RSNA and the organization is uniquely poised to convene the relevant stakeholders to address the complex, inter-related issues involved in extracting quantitative results from images. To be clinically useful and valuable, it is essential that quantitative results from imaging scans be reproducible. Major impediments to reproducibility are the current differentiation in imaging vendor products and image analysis tools as well as the independent activities of clinicians. Recognizing these fundamental issues, RSNA organized QIBA in 2007 to unite researchers, healthcare professionals and industry stakeholders to advance the use of quantitative imaging.

The QIBA initiative involves:

(1) stakeholder collaboration to identify needs, barriers, and solutions to develop and test consistent, reliable, valid, and achievable quantitative imaging results across imaging platforms, clinical sites, and time; and

(2) accelerating the development and adoption of hardware and software standards needed to achieve accurate and reproducible quantitative results from imaging methods.

One goal of QIBA is to see imaging scanners manufactured as measuring instruments, such as blood pressure cuffs or thermometers, that provide the same numerical reading no matter which vendor manufactures the device. Since the process of acquiring a clinical imaging scan is complex, this goal requires much coordinated activity among many stakeholders.

Validating a quantitative imaging biomarker requires identifying and characterizing all of the sources of error that affect the end measurement. A useful starting point is to group the factors affecting measurement into three broad classes defined by the imaging equipment, the software methods applied to measure the imaging feature, and the observer. These factors are interrelated, and each must be analyzed to assess their effect on systematic and random error.

QIBA committees develop QIBA Profiles (i.e., documents) of standardized specifications for image acquisition, collection, and post-processing. Profile Claims focus on a specific clinical application and are written using a statistically rigorous framework and language. Profile Details specify what must be achieved and/or what technical capabilities must be demonstrated in using the imaging device to realize the Claim.

QIBA Profiles take into consideration technical (product-specific) standards, user activities, and relationship to a clinically meaningful metric such as therapeutic response or other patient outcome measure. QIBA is also developing a compliance program to allow vendors and users to determine

whether equipment manufacturers and other "actors" are QIBA-Profile-compliant, using QIBA-branded or recommended phantoms (test objects), data sets, software, and other tools.

To develop a Profile, data relating to bias and variability of the biomarker measurement (referred to as groundwork data) are extracted from the literature and gaps in the published data necessary to understand the sources of variability are noted.

These gaps lead to QIBA projects to obtain such missing data. All data created by QIBA are to be made available to the public, either for secondary analyses by other investigators or to allow others to check and validate the conclusions drawn by QIBA participants. To facilitate such data availability, RSNA created the Quantitative Imaging Data Warehouse for use by QIBA committees. Details about all these QIBA activities follow in this report.

1. Aronson, Jeffrey (2005). "Biomarkers and Surrogate Endpoints". *British Journal of Clinical Pharmacology* 59 (5): 491–494. doi:10.1111/j.1365-2125.2005.02435.x. PMC 1884846. Retrieved 17 July 2013.
2. Definition of a biomarker. [Wikipedia website]. October 28, 2014. Available at: http://en.wikipedia.org/wiki/Biomarker. Accessed October 20, 2014.
3. Definition of Quantitative imaging. [RSNA.org website]. October 28, 2014. Available at: http://www.rsna.org/QIBA.aspx. Accessed October 20, 2014.

Who We Are

The forum created by QIBA for an organized and effective cooperative effort among key participants has advanced through the generous efforts of volunteer members from academia, the medical device, pharmaceutical and other business sectors, and government.

QIBA participants span a wide range of expertise including (but not limited to) clinical practice, clinical research, physics, engineering, statistics, marketing, senior management, regulatory, pharmaceutical, and computer science. The structure of QIBA explicitly includes the imaging device industry, which allows for precompetitive cooperation across all the vendors to achieve standardization of quantitative outputs.

Appendix 1 provides a list of the more than 150 entities (imaging hardware and software companies, academic institutions, federal agencies, professional organizations and other entities) across North America, Europe and Asia that have representatives participating in or monitoring QIBA activities. Although based primarily in the U.S., international participation in QIBA is substantial. In addition, QIBA-related meetings are held in both the U.S. and Europe.

From its inception, QIBA established communication with members of the FDA, NIH and NIST at several levels, and these essential interactions continue. FDA and NIST staff scientists participate in QIBA Committees and other working groups such as the QIBA Metrology Working Group, have *ex officio* representation on the QIBA Steering Committee, and receive QIBA documents for comment. FDA participation assures that the agency's perspective and wishes are incorporated into QIBA Profiles when appropriate.

QIBA exemplifies a collaborative Model for Partnership and Leadership. The QIBA structure has been developing and evolving over the past five years and is now widely recognized and respected by industry, academia and government agencies and is having a positive impact on imaging in clinical trials and clinical care.

The QIBA Kiosk provides a hub of information for RSNA annual meeting attendees.

Committee Reports by Quantitative Imaging Modality

CT Volumetry

QIBA CT Volumetry Technical Committee - Est: June 2008

Co-Chairs

- Samuel G. Armato, III, PhD - (University of Chicago)
- Gregory V. Goldmacher, MD, PhD - (ICON Medical Imaging)
- Lawrence H. Schwartz, MD - (New York Presbyterian Hospital/Columbia University Medical Center)

Purpose:

To investigate the technical feasibility and clinical value of quantifying changes over time in volume or other parameters such as lung density. Lung cancer was selected as the first example. Success will be defined as sufficiently rigorous improvements in CT-based outcome measures to (1) allow individual patients in clinical settings to switch treatments sooner if they are no longer responding to their current regimens, and (2) reduce the costs of evaluating investigational new drugs to treat lung cancer. This mechanism is cost-effective for stakeholders while simultaneously advancing the public health by promoting the use of measures which prove effective. If the specific aims are achieved in the lung

cancer example, then the paradigm will be extrapolated to other clinical scenarios where volumetry or similar measures are medically meaningful.

Activities and Deliverables

QIBA Profile: CT Tumor Volume Change v2.2 (Publicly Reviewed Version)

- CT Volumetry Technical Committee. CT Tumor Volume Change Profile, Quantitative Imaging Biomarkers Alliance. Version 2.2. Publicly Reviewed Version. QIBA, August 8, 2012. Available at *RSNA.org/QIBA*

Claim: Measure Change in Tumor Volume

- A measured volume change of more than 30% for a tumor provides at least a 95% probability that there is a true volume change: P(true volume change > 0% | measured volume change >30%) > 95%.
    - Note, the claim is undergoing revision for the next version of the Profile. Part of this process is the reformulation of the claim to comply with the standards set by the QIBA Metrology Working Group.
- This claim holds when the given tumor is measurable (i.e., tumor margins are sufficiently conspicuous and geometrically simple enough to be recognized on all images in both scans), and the longest in-plane diameter of the tumor is 10 mm or greater. Volume change refers to proportional change, where the percentage change is the difference in the two volume measurements divided by the average of the two measurements. By using the average instead of one of the measurements as the denominator, asymmetries in percentage change values are avoided.
- For details on the derivation and implications of the claim, refer to Appendix B in the Profile.
- While the claim has been informed by an extensive review of the literature, it is currently a consensus claim that has not yet been fully substantiated by studies that strictly conform to the profile specifications. There have not yet been a sufficient number of studies performed using the Profile acquisition criteria. The expectation is that during a field test, data on the actual field performance will be collected and changes made to the claim or the details accordingly.
- The Profile is currently under public review. For compliance, the committee is currently preparing a checklist of actions for each "actor" to establish compliance. The compliance procedures have been divided into those related to patient handling activities, those related to scan acquisition and reconstruction, and those related to image analysis. Each set of procedures is being defined by dedicated subgroups of the committee. Procedures for claiming compliance to the Image Data Acquisition and Image Data Reconstruction activities have been provided (See Section 4 in the Profile). Procedures for claiming compliance to the Image Analysis activity are proposed in draft form and will be revised in the future.

Funded projects

Round 1 of funding (2011-2012):

Project title: Inter-scanner/Inter-clinic Comparison of Reader Nodule Sizing in CT Imaging of a Phantom

PI/Institution: Michael McNitt-Gray, PhD (UCLA)

PI/Institution: David Clunie, MBBS (CoreLab Partners)

Publications:

- Petrick N, Kim HJG, Clunie D, Borradaile K, Ford R, Zeng R, Gavrielides MA, et al. Comparison of 1D, 2D, and 3D Nodule Sizing Methods by Radiologists for Spherical and Complex Nodules on Thoracic CT Phantom Images. *Academic Radiology*, 2014; 21(1), 30–40. http://dx.doi.org/10.1016/j.acra.2013.09.020

Meeting Presentations:

- Petrick N, Kim HJG, Clunie D, Borradaile K, Ford R, Zeng R, Gavrielides M, et al. Evaluation of 1D, 2D and 3D Nodule Size Estimation by Radiologists for Spherical and Non-spherical Nodules Through CT Thoracic Phantom Imaging. *Medical Imaging, 2011;* 79630D 1–7. Lake Buena Vista, FL: SPIE. doi:10.1117/12.878265

Project title: Assessing Measurement Variability of Lung Lesions in Patient Data Sets

PI/Institution: Michael McNitt-Gray, PhD (UCLA)

Meeting Presentations:

- McNitt-Gray M, Kim HJG, Zhao B, Schwartz L, Clunie D, Borradaile K, Byrne K, et al. Estimating the Minimum Detectable Change of Lung Lesions Using Patient Datasets Acquired Under a "No Change" Condition. RSNA Annual Meeting, 2011, Chicago.

Project title: Validation of Volumetric CT as a Biomarker for Predicting Patient Survival

PI/Institution: Binsheng Zhao, DSc (Columbia University)

Publications:

- Zhao B, Lee S, Lee HJ, Tan Y, Qi J, Persigehl T, Mozley PD and Schwartz LH. Variability in assessing treatment response: metastatic colorectal cancer as a paradigm. *Clin Cancer Res*. Published Online First on April 29, 2014; doi: 10.1158/1078-0432.

Meeting Presentations:

- Zhao B, Lee S, Lee H, Qi J, Persigehl T, Tan Y, Mozley D, Buckler A, Sullivan D, Schwartz LH, Inter-reader and Intra-reader Variability in Assessing Change of Total Tumor Volume. Computer Assisted Radiology and Surgery (CARs*), Joint Congress,* 2013, June 26-29, Heidelberg, Germany.

Posters:

- Zhao B, Lee S, Lee HJ, Qi J, Persigehl T, Tan T, Schwartz LH. Relationship of Variability in Tumor Measurement and Response. *American Society of Clinical Oncology (ASCO) Annual Meeting,* June 1-5, 2012, Chicago.
- Zhao B, Lee S, Qi J, Mozley PD, Mauro D, Schwartz LH. Minor Response Rate Predicts Patient Survival. *ASCO Annual Meeting,* June 2-6, 2013, Chicago.

Project title: Development of Assessment and Predictive Metrics for Quantitative Imaging in Chest CT

PI/Institution: Ehsan Samei, PhD (Duke)

Publications:

- Chen B, Richard S, Barnhart H, Colsher J, Amurao M, Samei E. Quantitative CT: technique dependency of volume assessment for pulmonary nodules. *Physics in Medicine and Biology* 57: 1335–1348, 2012.
- Chen B, Barnhart H, Richard S, Robins M, Colsher J, Samei E. Volumetric quantification of lung nodules in CT with iterative reconstruction (ASiR and MBIR) *Medical Physics* 40(11): 111902 - 111202-10, 2013.
- Chen B, Christianson O, Wilson J, Samei E. Assessment of volumetric noise and resolution performance for linear and nonlinear CT reconstruction methods. *Medical Physics* 41, 071909, 2014.
- Chen B, Samei E. Developing a prediction model for volume quantification performance in computed tomography. *Medical Physics* (in press, 2014).

Project title: Quantifying Variability in Measurement of Pulmonary Nodule (solid, part-solid and ground glass) Volume, Longest Diameter and CT Attenuation Resulting from Differences in Reconstruction Thickness, Reconstruction Plane, and Reconstruction Algorithm.

PI/Institution: Kavita Garg, MD (University of Colorado)

Publications (in preparation):

- Scherzinger A, Garg K, Kim HJG, et al. Accuracy and Reproducibility of Semi-automated 3D Quantitative Measurements of Part-solid Nodules in a Thoracic CT Phantom. Planning submission to *Academic Radiology.*
- Garg K, Scherzinger A, Kim HJG, et al. Quantitative Measurement of Part-Solid Nodule Size on CT in a Chest Phantom: Effect of Dose on Accuracy. Planning submission to *Investigative Radiology*-special issue

Meeting Presentations:

- Scherzinger A, Garg K, Kim G, et al. Quantitative Measurement of Part-Solid Nodule Size on CT in a Chest Phantom: Effect of Dose on Accuracy, *RSNA 2013*.

Round 2 of funding (2012-2013):

Project title: Extension of Assessing Measurement Variability of Lung Lesions in Patient Data Sets: Variability Under Clinical Workflow Conditions

PI/Institution: Michael McNitt-Gray, PhD (UCLA)

PI/Institution: David Clunie, MBBS (CoreLab Partners)

Project title: Comparative Study of Algorithms for the Measurement of the Volume of Lung Lesions: Assessing the Effects of Software Algorithms on Measurement Variability

PI/Institution: Hyun (Grace) Kim, PhD (UCLA)

Project title: Impact of Dose Saving Protocols on Quantitative CT Biomarkers of COPD and Asthma

PI/Institution: Sean Fain, PhD (University of Wisconsin)

Round 3 of funding (2013-2014):

Project title: Second 3A Statistical and Image Processing Analysis

PI/Institution: Andrew Buckler, MS (Elucid Bioimaging, Inc.)

Publications: A paper based on the findings of the clinical study is currently in progress.

Project title: Phantoms for CT Volumetry of Hepatic and Nodal Metastasis

PI/Institution: Binsheng Zhao, DSc (Columbia University)

QIBA CT Volumetry Subcommittee 3A (algorithm challenges) - Est: November, 2011

Chair

- Maria Athelogou, PhD - (Definiens, Munich, Germany)

Purpose: The primary aim of the QIBA Volumetric Study 3A is to estimate inter- and intra-algorithm variability of volume estimation from CT scans. Participants include academic and commercial algorithm developers.

The study is not intended to determine which image analysis algorithm is best, but rather to assess individual algorithm performance against a defined test set of cases, providing knowledge to inform the QIBA Profile specifications.

QIBA Lung Nodule Assessment in CT Screening Writing Group - Est: September, 2012

Co-Chairs:

- Samuel G. Armato, III, PhD - (University of Chicago)
- David S. Gierada, MD - (Washington University in St. Louis)
- James L. Mulshine, MD - (Rush University Medical Center)

Purpose: To define evidence-based consensus standards and processes for CT imaging in the setting of lung cancer screening, to allow for quantification of biologically meaningful longitudinal volume changes with acceptable range of variance across vendor platforms. The concept is similar to the CT volumetry Profile for advanced cancer, but in this case, the QIBA Profile is being optimized for the small nodules detected on CT screening for lung cancer.

Activities and Deliverables

In progress:
QIBA Profile: CT Volumetry: Lung Nodule Volume Assessment and Monitoring in Lung Cancer Screening, 02.05.2014

The experimental data of group members and also literature data needed to establish the claim is under review. The draft specifications and accompanying discussions have gone through multiple revisions and are nearly final. We are currently engaging with manufacturer's representatives to obtain guidance regarding technical parameters for individual scanner models for quantitative applications.

QIBA Lung Density Technical Committee - Est: June 2009

Chair:
- Philip F. Judy, PhD - (Brigham and Women's Hospital and Harvard Medical School)

Purpose: Reduce and characterize bias and variance across CT manufacturers, software versions, and sites in support of quantitative CT lung densitometry and morphology.

Initial Objectives:

- Characterize the bias and precision of phenotyping and progression measurements in emphysema and asthma.
- Classify phenotype and assess longitudinal changes as medically meaningful surrogates for health status.
- Compare the sensitivity of CT measurements to spirometry and other accepted measures.
- Determine if progressive lung disease can be detected significantly sooner with quantitative imaging techniques than with currently accepted methods.

Activities and Deliverables

A draft profile and claim development are in progress, pending critical evaluation of literature, for a lung density protocol. The acquisition and reconstruction specification of CT images has been completed and is being evaluated by a working group of vendor scientists who are developing compliance procedures using the COPDGene Phantom. The image analysis section of Profile also needs to be completed.

Funded projects

Round 2 of funding (2012-2013):

Project title: Impact of Dose Saving Protocols on Quantitative CT Biomarkers of COPD and Asthma

PI/Institution: Sean Fain, PhD (University of Wisconsin)

Airway measurements are not accurate with reconstruction parameters currently used in ongoing clinical research studies. Improved spatial resolution enables accurate measurements by reduced DFOV and higher resolution Kernel. The combination of ASIR with higher spatial resolution reconstruction shows promise to reduce X-ray dose and improve qCT of lung airways.

Publications:

Rodriguez A; Ranallo FN; Judy PF; et. al., CT Reconstruction Techniques for Improved Accuracy of Lung CT Airway Measurement; submitted for publication.

Meeting Presentations:

Rodriguez A; Ranallo FN; Judy PF; et. al., Improved Airway Measurement Accuracy for Low Dose Quantitative CT (qCT) Using Statistical (ASIR), at Reduced DFOV, and High-Resolution Kernels in a Phantom and Swine Model; American Association of Physicists in Medicine (AAPM) Annual Meeting, 2014, Austin, Texas.

Posters:

Rodriguez A; Ranallo FN; Judy PF; et. al., Airway Measurement Accuracy For Low Dose Quantitative CT (qCT) Using Statistical (ASIR), And Model Based Reconstruction Techniques (Veo), American Thoracic Society (ATS) International Conference, 2014,San Diego Convention Center [Poster Board # 618] [Publication Number: A2395].

Collaborations:

The Committee has collaborated with the Society of Thoracic Radiology (STR) to present one-day conferences on QCT of the lung. These conferences were held before the STR Annual Meetings in 2012 and 2014. The Committee also had a half-day session during the 6th International Workshop for Pulmonary Functional Imaging, July 18-20, 2013, Madison, Wis.

The Committee is working with NIST scientists to design an improved COPDGene Phantom. The additional NIST-identified foams allow calibration of CT numbers of lower density substances such as the lung. The improved phantom is available from The Phantom Laboratory.

The Committee plans to evaluate lower radiation dose protocols and will determine the impact of AEC and IR for qCT of lung density and airway measurements across scanner platforms. Members hope to establish equivalent performance for AEC and IR across the major vendor platforms represented in the installed base of 64 slice systems (e.g., GE, Siemens, Philips, Toshiba).

Magnetic Resonance imaging (MR)

QIBA Perfusion, Diffusion and Flow-MRI (PDF-MRI) Technical Committee - Est: June 2008

Co-Chairs:

- Marko K. Ivancevic, PhD - (Philips Healthcare)
- Mark Rosen, MD, PhD - (University of Pennsylvania)
- Gudrun Zahlmann, PhD - (F. Hoffman-La Roche, Ltd)

Purpose: To make DCE and DWI image acquisition across different vendors more comparable by protocol specification and standardized phantom calibration.

Activities and Deliverables

QIBA Profile. DCE-MRI Quantification v1.0 (Publicly Reviewed Version)

Claim:

- Quantitative microvascular properties, specifically transfer constant (Ktrans) and blood-normalized initial-area-under-the-gadolinium-concentration curve (IAUGCBN), can be measured from DCE-MRI data obtained at 1.5T using low-molecular-weight extracellular gadolinium-based contrast agents with a 20% within-subject coefficient of variation for solid tumors at least 2 cm in diameter.*
- Profile specified for use with patients with malignancy, for the following indicated biology: primary or metastatic, and to serve the following purpose: therapeutic response.
- A 20% within-subject coefficient of variation is based on a conservative estimate from the peer-reviewed literature. In general, this suggests that a change of approximately 40% is required in a single subject to be considered significant.

QIBA DWI Profile v1.09

Claims: (draft)

- Biomarker measurand: in vivo tissue water mobility– commonly referred to as the apparent diffusion coefficient (ADC)
    - Context of use: ADC mapping to gain insight into microstructural and compositional changes in tumors due to treatment
        i. Cross-sectional measurement: Disease state determination via absolute ADC value (thresholds)
            1. Index: the ADC value at isocenter
            2. Bias Profile: When measuring an ice-water phantom at isocenter, the ADC measurement should exhibit no more than a 5% bias from the gold standard value of 1.1×10^{-9} m^2/s
            3. Precision Profile: When acquiring ADC values in solid tumors greater than 1 cm in diameter, or twice the slice thickness (whichever is greater), one can characterize *in vivo* diffusion with at least a 15% test/retest coefficient of variation, intra-scanner and intra-reader
        ii. Longitudinal measurement: measurement of ADC as an indicator of treatment response
            1. Index: the ADC value at isocenter
            2. Bias Profile: When measuring an ice water phantom at isocenter, the ADC measurement should exhibit no more than a 5% bias from the gold standard value of 1.1×10^{-9} m^2/s

3. Precision Profile: When acquiring ADC values in solid tumors greater than 1 cm in diameter, or twice the slice thickness (whichever is greater), once can character *in vivo* diffusion with at least a 15% test/retest coefficient of variation, intra-scanner and intra-reader

QIBA Profile DCE-MRI, v2.0 – Draft in progress.

DCE Profile v 1.0 has been publicly reviewed and is available for public use. Currently, a compliance document which will supplant section IV of DCE Profile v 1.0 is being drafted and is expected to be completed by the end of 2014.

Funded projects

Round 1 of funding (2011-2012):

Project title: DCE-MRI Phantom Fabrication, Data Acquisition and Analysis, and Data Distribution

PI/ Institution: Edward Jackson, PhD (MDACC)

Meeting Presentations:

- Bosca RJ, Ashton E, Zahlmann G, Jackson EF. RSNA Quantitative Imaging Biomarkers Alliance (QIBA) DCE-MRI Phantom: Goal, Design, and Initial Results. Proceedings of the RSNA 98th Scientific Assembly and Annual Meeting (Oral Presentation), 11/2012

Posters: RSNA QIBA PDF-MRI Technical Committee posters (2011 and 2012)

Other:

- Example datasets uploaded for testing of QIDW. Four copies of phantom fabricated, filled and cross-validated at 1.5T and 3.0T. Three copies were released for site qualification use (ACRIN 6701, PI: Rosen, Phase II Project)

Project title: Software Development for Analysis of QIBA DCE-MRI Phantom Data

PI/ Institution: Edward Ashton, PhD (VirtualScopics)

Status: Software executable delivered to QIBA/RSNA, along with manual for installation and use.

Project title: Digital Reference Object for DCE-MRI Analysis Software Verification

PI/ Institution: Daniel Barboriak, MD (Duke)

Publications:

- Barboriak DP, Price R. Digital Reference Objects for Dynamic Contrast-enhanced MRI. *QIBA Newsletter,* January 2013: Volume 5, Number 1.

- Huang W, Li X, Chen Y, Chang MC, et. al., Variations of Dynamic Contrast-Enhanced Magnetic Resonance Imaging in Evaluation of Breast Cancer Therapy Response: A Multicenter Data Analysis Challenge. *Translational Oncology*, in press

Meeting Presentations:

- Cron GO, Sourbron S, Barboriak DP, et. al., Bias and Precision of Three Different DCE-MRI Analysis Software Packages: A Comparison Using Simulated Data, Computer presentation at ISMRM 2014, Milan

Posters: RSNA QIBA posters

Other:

- DROs are online on the QIDW and also at https://sites.duke.edu/dblab/qibacontent/;
- Also, reports on software have been developed and distributed to DRO evaluation participants.

Round 2 of funding (2012-2013):

Project title: Test-Retest Evaluation of Repeatability of DCE-MRI and DWI in Human Subjects

PI/ Institution: Mark Rosen, MD, PhD (University of Pennsylvania)

Status: Accrual in progress.

Round 3 of funding (2013-2014):

Project title: DW-MRI ADC Phantom

PI/ Institution: Michael Boss, PhD (NIST - Boulder, CO)

Meeting Presentations:

- Thermally Stabilized Isotropic Diffusion Phantom for Multisite Assessment of Apparent Diffusion Coefficient Reproducibility; AAPM Annual Meeting, July 2014
- Temperature-controlled Isotropic Diffusion Phantom with Wide Range of Apparent Diffusion Coefficients for Multicenter Assessment of Scanner Repeatability and Reproducibility; ISMRM Annual Meeting, May 2014
- Tissue Water Mobility by MRI: Diffusion Coefficient Reproducibility with a Temperature-Controlled Phantom at University of Oregon Diffusion NMR; DOSY and MRI Workshop, April 2014

Posters: QIBA Perfusion, Diffusion, & Flow MRI Technical Committee: Current Status (RSNA 2013)

Project title: Software Development for Analysis of QIBA DW-MRI Phantom Data

PI/ Institution: Thomas Chenevert, PhD (University of Michigan)

Status: In progress.

Project title: DCE-MRI Phantom Study to Evaluate the Impact of Parallel Imaging and B1 Inhomogeneities at Different MR Field Strengths of 1.0T, 1.5T, and 3.0T

PI/ Institution: Thorsten Persigehl, MD (University Hospital Cologne, Germany)

Status: In progress.

Project title:
Development of a Tool to Evaluate Software Using Artificial DCE-MRI Data and Statistical Analysis

PI/ Institution: Hendrik Laue, PhD(Fraunhofer MEVIS, Germany)

Status: Software in beta testing.

Collaborations:

- Collaboration with QuIC-ConCePT to implement DW-MR Profile in liver mets clinical trial
- Collaboration with ACRIN to implement DCE-MRI Profile in prostate cancer clinical trial

Co-Chairs:

- Edgar DeYoe, PhD - (Medical College of Wisconsin)
- Cathy Elsinger, PhD - (NordicNeuroLab, Inc.)
- Jeffrey Petrella, MD - (Duke University Medical Center)

Purpose: To create and support implementation of a QIBA Profile for functional MRI as a pre-surgical assessment tool.

Activities and Deliverables

Draft Profile: Mapping of Brain Regions Using Blood Oxygenation Level Dependent (BOLD) functional MRI as a Pre-surgical Assessment Tool. Latest version updated: June 4, 2014

Draft Claims:

Claims characterizing *r*eproducibility of BOLD response

B. Biomarker measurand: Local T2* MRI contrast change (reflecting a hemodynamic response to change in brain activity) – commonly referred to as the BOLD fMRI signal (the biomarker is a measurable physical property)
    a. Context of use: Preoperative fMRI mapping of eloquent cortex for treatment planning/guidance
    1. Cross-sectional measurement: Localization of BOLD signal as index of eloquent cortex (motor, language, and/or visual cortical areas)
        1. Index: the center of mass of activation of a focus of interest
            - Bias Profile:
            - Precision Profile
                - On a test-retest basis, the center of mass of activation of a focus of interest can be determined with a 5mm repeatability coefficient
        2. Index: the spatial extent half-maximum border of activation clusters (to be defined for normalized and non-normalized parametric maps)
            - Bias Profile:
            - Precision Profile:
                - On a test-retest basis the spatial location of the half-maximum border of an activation cluster can be determined with a 10mm repeatability coefficient
    2. For each index, should also indicate Reproducibility (Intra-class Correlation Coefficient [ICC]; Concordance Correlation Coefficient [CCC], Reproducibility Coefficient [RDC]):
        1. Specify conditions, e.g.,

- Measuring system variability (hardware and software)
- Site variability
- Operator variability (Intra- or Inter-reader)
- Time interval (across days/weeks etc.)

ii. Longitudinal change measurement (if specified)
   0. List Indices: (as above, including sub-parts)

Profile V1.0 is in the draft stage. The committee has narrowed the focus to presurgical mapping of the motor cortex and is refining the claims to this clinical context. Likewise, members are in the process of completing Section 3 – Profile Details – specific to the mapping of motor cortex. To inform compliance procedures, members are conducting groundwork studies focused on software analysis specifications.

Bias Subcommittee. Meets on alternate weeks, bimonthly, to focus on the issue of bias in our measurand. This activity will inform our Profile claims definition and guide development of methodological sequences for image analysis that best achieve the claims.

Funded projects

Round 1 of funding (2011-2012):

Project title: Quantitative Measures of fMRI Reproducibility for Pre-Surgical Planning

PI/Institution: Edgar DeYoe, PhD (Medical College of Wisconsin)

Posters:

- DeYoe E, Voyvodic JT, Elsinger C, et. al., Reproducibility of Functional MRI – Progress Towards Profile Development. RSNA Annual Meeting 2011, Chicago. (QIBA Poster)
- DeYoe E, Voyvodic JT, Pillai J, et. al., Establishing A More Quantitative Approach for Clinical Application. RSNA Annual Meeting 2012, Chicago. (QIBA Poster)
- DeYoe, E, Voyvodic JT, Pillai J, et. al., BOLD fMRI – Establishing a More Quantitative Approach for Clinical Application. American Society of Functional Neuroradiology Annual Meeting, 2013, Charleston.

Other: Data sets are being uploaded to an fMRI Community on the QIDW.

Project title: Quantitative Measures of fMRI Reproducibility for Pre-Surgical Planning-Development of Reproducibility Metrics

PI/Institution: James Voyvodic, PhD (Duke)

Publications:

- Voyvodic JT. Reproducibility of Single-Subject fMRI Language Mapping with AMPLE Normalization. *J. Magn. Reson. Imaging*, 2012; 36:569-80.

Posters:

- DeYoe E, Voyvodic JT, Elsinger C, et. al., Reproducibility of Functional MRI–Progress Towards Profile Development. RSNA Annual Meeting 2011, Chicago. (QIBA Poster)
- DeYoe E, Voyvodic JT, Pillai J, et. al., Establishing A More Quantitative Approach for Clinical Application. RSNA Annual Meeting 2012, Chicago. (QIBA Poster)
- DeYoe, E, Voyvodic JT, Pillai J, et. al., BOLD fMRI – Establishing a More Quantitative Approach for Clinical Application. American Society of Functional Neuroradiology Annual Meeting, 2013, Charleston.

Round 2 of funding (2012-2013):

Project title: Validation of Breath Hold Task for Assessment of Cerebrovascular Responsiveness and Calibration of Language Activation Maps to Optimize Reproducibility

PI/ Institution: Jay Pillai, MD (Johns Hopkins)

Publications:

- Zacà D, Jovicich J, Nadar SR, et. al., Cerebrovascular Reactivity Mapping in Patients with Low Grade Gliomas Undergoing Pre-Surgical Sensorimotor Mapping with BOLD fMRI. *J Magn Reson Imaging;* 2013.

Posters:

- DeYoe E, Voyvodic JT, Pillai J, et. al., Establishing A More Quantitative Approach for Clinical Application. RSNA Annual Meeting 2012, Chicago. (QIBA Poster)
- Zacà D, Nadar SR, Jovicich J, Pillai JJ. Cerebrovascular Reactivity-based Calibration of Presurgical Motor Activation Maps to Improve Detectability of the BOLD Signal in Patients with Perirolandic Brain Tumors. International Society for Magnetic Resonance in Medicine, 2013 Annual Meeting (April 20-26, 2013, Salt Lake City, Utah).

Round 3 of funding (2013-2014):

Project title: fMRI Digital Reference Objects for Profile Development and Verification

PI/Institution: Edgar DeYoe, PhD (Medical College of Wisconsin)

Meeting Presentations:

Posters: Mohamed F, Soltysik D, DeYoe E, et. al., Creation of fMRI Digital Reference Objects with Multiple Sources of Signal Variance. RSNA Annual Meeting 2013, Chicago. (QIBA Poster)

Collaborations:

- DICOM WG-16 - 5/2014 WG-16 fMRI subcommittee established. Goal is to prioritize information which can be expressed in DICOM to enhance storage and transmission of fMRI data.

Nuclear Medicine (NM)

QIBA FDG-PET / CT Technical Committee - Est: June 2008

Co-Chairs:

- Ling X. Shao, PhD - (Philips Healthcare)
- John J. Sunderland, PhD - (University of Iowa)
- Richard L. Wahl, MD - (Mallinckrodt Institute of Radiology, Washington University)

Purpose:

- Foster adoption of pragmatic standards for accurate and reproducible longitudinal quantitation of biologic parameters with clinical relevance, such as SUV on FDG-PET scans

Activities and Deliverables

FDG-PET Profile – Public review

QIBA Profile: QIBA Profile: FDG-PET/CT as an Imaging Biomarker Measuring Response to Cancer Therapy (Publicly Reviewed Version)

Claim: Measure Change in SUV

If Profile criteria are met, tumor glycolytic activity as reflected by the maximum standardized uptake value (SUVmax) should be measurable from FDG-PET/CT with a within-subject coefficient of variation of 10-12%.

FDG-PET UPICT Protocol – Public review

http://rsna.org/uploadedFiles/RSNA/Content/Science_and_Education/QIBA/UPICT_FDG-PET_Protocol_ver08July2014.pdf

Funded projects

Round 1 of funding (2011-2012):

Project title: Meta-analysis to Analyze the Robustness of FDG SUV Changes as a Response Marker, Post and During Systemic and Multimodality Therapy, for Various Types of Solid Extra-cerebral Tumors

PI/ Institution: Otto Hoekstra, MD (VU Medical Center, The Netherlands)

Meeting Presentations:

- Abstract #1325408, Vincent A, RizviN, Tinteren H, Riphagen, Hoekstra O, "Towards qualification of FDG PET as a biomarker of response to cancer therapy: A meta-analysis." SNMMI 2012.

- Abstract # 1633580, Oo JH, Leal J, Tahari A, Baker L, Wahl RL, "Early treatment response by FDG PET in patients with the Ewing sarcoma family of tumors predicts survival." SNMMI 2013.

Project title: QIBA FDG-PET/CT Digital Reference Object Project

PI/Institution: Paul Kinahan, PhD (University of Washington)

Publications: Submitted to *Radiology*; in revision.

Meeting Presentations: Poster and display station presentations at the Quantitative Reading Room, RSNA 2012; oral presentation at 2012 SNMMI meeting.

Project title: Analysis of SARC 11 Trial PET Data by PERCIST with Linkage to Clinical Outcomes

PI/Institution: Richard Wahl, MD (Johns Hopkins University School of Medicine)

Publications: Manuscript submitted to *JCO*

Meeting Presentations: Oral presentation, SNMMI 2013 Vancouver

Round 2 of funding (2012-2013):

Project title: Personnel Support for FDG-PET Profile Completion (Profile Editor)

PI/Institution: Eric Perlman, MD (Perlman Advisory Group)

Meeting Presentations: 2014 SNM meeting

Posters: SNMMI 2014, St. Louis

Project title: Evaluation of the Variability in Determination of Quantitative PET Parameters of Treatment Response Across Performance Sites and Readers

PI/Institution: Richard Wahl, MD (Johns Hopkins University School of Medicine)

Meeting Presentations: RSNA 2013, oral presentation

Posters: SNMMI 2014, St. Louis

Project title: PERCIST Validation

PI/Institution: Otto Hoekstra, MD (VU Medical Center, The Netherlands)

Status: Manuscript in progress.

Project title: Evaluation of FDG-PET SUV Covariates, Metrics, and Response Criteria

PI/Institution: Jeffrey Yap, PhD (Dana-Farber Cancer Institute)

Status: Manuscript in progress.

Round 3 of funding (2013-2014):

Project title: FDG-PET/CT Profile Field Test

PI/ Institution: Timothy Turkington, PhD (Duke University)

Status: In progress.

Project title: FDG-PET/CT Digital Reference Object (DRO) Extension

PI/ Institution: Paul Kinahan, PhD (University of Washington)

Status: In progress.

Collaborations:

Joint workshop with Society of Nuclear Medicine and Molecular Imaging (SNMMI) to develop the FDG-PET UPICT Protocol.

The NCI Quantitative Imaging Network (QIN) is using the FDG-PET/CT Digital Reference Object as a test step during a grand challenge project for PET segmentation.

QIBA PET Amyloid Profile Writing Group - Est: December, 2013

Co-Chairs:

- Satoshi Minoshima, MD, PhD - (University of Utah)
- Eric S. Perlman, MD - (Perlman Advisory Group, LLC)
- Anne M. Smith, PhD - (Siemens)

Purpose:
To develop a QIBA Profile for quantitative assessment of PET amyloid imaging agents.

Activities and Deliverables

There is a draft Profile, and current outline of the Claim is:

- SUVr will be the measurand
- The claim will have two components
    - Cross-sectional: single subject scan
    - Longitudinal: following subject over time

Due to the complexity of having multiple PET Amyloid tracers, a subgroup, the Test-retest Group, has been formed including academics and industry representatives from all of the major PET Amyloid tracer vendors. This group will evaluate the published data on amyloid imaging precision, to

determine what level of precision can be claimed in the Profile. The committee's goal is to have a final draft Profile by December 2014.

Collaborations:
RSNA QIBA is now an affiliate of GAAIN (Global Alzheimer's Association International Network)

QIBA FDG-PET Reporting Standards Writing Group - Est: March, 2014

Co-Chairs:
- Paul E. Kinahan, PhD, FIEEE - (University of Washington)
- Paul Marsden, PhD - (King's College London, UK)

Purpose:
To summarize the study characteristics that would need to be reported for a PET quantitative imaging biomarker in order for the study to be repeated and/or usefully included as part of a future meta-analysis.

Activities and Deliverables

This is a multi-group activity, involving members from QIBA, QIN, Cancer Research UK, and ECOG-ACRIN and others.

The committee is planning two deliverables:

- A guideline listing what data that should be reported as part of a quantitative imaging biomarker study
- A companion paper that provides the following: motivation, rational for data to be reported, proposed methods of adoption.

These activities are intended to extend to other quantitative imaging biomarkers.

A presentation was made at the 2014 AAPM Annual Meeting, Austin.

Ultrasound Shear Wave Speed (SWS)

QIBA Ultrasound Shear Wave Speed Technical Committee - Est: March 2012

Co-Chairs:
- Brian Garra, MD - (Washington DC VA Medical Center/FDA)
- Timothy J. Hall, PhD - (University of Wisconsin, School of Medicine & Public Health)
- Andy Milkowski, MS - (Siemens)

Purpose: To create and support implementation of a QIBA Profile for an ultrasound shear wave speed (SWS) quantitative biomarker for liver disease.

Activities and Deliverables

Major efforts center on publishing Phase I Phantom Study results, continuing to understand and accounting for sources of bias in SWS estimation with ultrasound imaging systems, continuing to determine sources of variance in these estimates and minimizing those contributions, and continuing to draft the Protocol and Profile.

Funded projects

Round 3 of funding (2013-2014):

Project title: Phase 2 Phantom Study with Inelastic, SWS-dispersive Media

PI/ Institution: Timothy J. Hall, PhD (University of Wisconsin, Madison)

Status: In progress.

Meeting Presentations: See, "Ultrasound Shear Wave Speed – Phantom Development Subcommittee" report below.

Project title: A Pilot Study of the Effect of Steatosis and Inflammation on Shear Wave Speed for the Estimation of Liver Fibrosis Stage in Patients with Diffuse Liver Disease

PI/Institution: Anthony Samir, MD, MPH (Massachusetts General Hospital)

Status: Project underway; subject recruitment goals exceeded. Data analysis September / October 2014.

Meeting Presentations: See, "Clinical Applications & Biological Targets Subcommittee" report below.

Project title: Numerical Simulation of Shear Wave Speed Measurements in the Liver

PI /Institution: Mark Palmeri, MD, PhD (Duke University)

Status: In progress.

Meeting Presentations: See *"Ultrasound Shear Wave Speed - System Dependencies Subcommittee"* report below.

QIBA Ultrasound Shear Wave Speed - System Dependencies Subcommittee - Est: May 2012

Co-Chairs:

- Mark L. Palmeri, MD, PhD - (Duke University)
- Keith A. Wear, PhD - (U.S. Food and Drug Administration [FDA])

Purpose: To establish a set of standards to allow for comparison of SWS across vendors.

(Note: In 2014, the FDA provided funding to the Duke University investigators to support the numerical simulation effort).

Activities and Deliverables

Meeting presentations and posters

Carson P; Milkowski A; Hall TJ; et. al., RSNA QIBA Ultrasound Shear Wave Speed: Sources of Variability in Phantoms, Simulations and Humans, *Biomedical Engineering Society,* San Antonio, Texas, 2014

Hall TJ, Garra BS, Milkowski A, et. al., RSNA's QIBA Effort To Develop And Validate Cross-System Shear Wave Speed Measurements For Staging Liver Fibrosis, Eleventh International Tissue Elasticity Conference, Deauville, France, Oct 2, 2012.

Jiang J, McAleavey S, Langdon J, Palmeri M. Development of Open-Source Tools to Validate Shear Wave Imaging: An Integrated QIBA Effort, 13th International Tissue Elasticity Imaging Conference, September 07-10, 2014 Snowbird, Utah.

Milkowski A, Hall TJ, Garra B, et. al., RSNA/QIBA Ultrasound Shear Wave Speed Estimation inelastic Phantoms: Sources and Magnitude of Variability in a Multicenter Study, American Institute of Ultrasound in Medicine Conference, March 31, 2013,

Milkowski A, Hall TJ, Andre M, et. al., Ultrasound Shear Wave Speed Estimation in Elastic Phantoms: Sources and Magnitude of Variability in a QIBA Multicenter Study**,** RSNA Annual Meeting, Chicago, 2013

Palmeri M, Deng Y, Rouze N, Nightingale K. Modulation of Acoustic Radiation Force-Induced Shear Wave Spectral Content by Spatial Beamwidths and Excitation Duration, 39th International Symposium on Ultrasonic Imaging and Tissue Characterization, June 09-11, 2014.

Palmeri M, Deng Y, Rouze N, et. al., Dependence of Shear Wave Spectral Content on Acoustic Radiation Force Excitation Duration and Spatial Beamwidth, IEEE Symposium on Ultrasonics, September 2014, Chicago.

Software or Datasets

Mendeley Literature Database: http://www.mendeley.com/groups/2396601/qiba-sws/

Finite element simulation data of elastic materials corresponding to the Phase I phantoms, simulated for a variety of excitation configurations, have been available publicly for the past year, hosted on a Duke web server (https://github.com/RSNA-QIBA-US-SWS/QIBA-DigitalPhantoms). Very recently, those data have been transferred to the QIBA QIDW. The data, posted in Matlab® format, also has accompanying documentation to allow anyone to replicate the simulations or adapt them for their specific imaging configurations.

QIBA Ultrasound Shear Wave Speed – Phantom Development Subcommittee - Est: May 2012

Co-Chairs:

- Brian Garra, MD - (Washington DC VA Medical Center/FDA)
- Timothy J. Hall, PhD - (University of Wisconsin, School of Medicine & Public Health)

Purpose: To determine the appropriate ultrasound elastography phantom material properties and phantom design needed to adequately assess SWS measurement performance.

Activities and Deliverables

Meeting Presentations:

Emelianov S, Hall TJ, Bouchard R, Ultrasound Elasticity, Educational Course, AAPM Annual Meeting, 2014 Austin, TX, Med Phys, WE-E-9A-1.

Garra, B, (2013). Ultrasound Measurements and FDA Criteria for Display of New Quantitative Measures. RSNA 2013 (p. abstract only), Short Course RC825A, Retrieved from *rsna2013.rsna.org/program/details/?emID=12020945.*

Hall TJ, Milkowski A, Garra B, et. al., RSNA/QIBA: Shear Wave Speed as a Biomarker for Liver Fibrosis Staging, *Proc. IEEE Ultrason. Symp. Proceedings* 397-400, ISSN: 1948-5719, 2013. Prague, Czech Republic, 2013. (also a poster)

Hall TJ, Garra B, Milkowski A, et. al., QIBA Shear Wave Speed Imaging: Making It Much More Reproducible, American Institute of Ultrasound in Medicine Conference, 2013.

Hall TJ, RSNA Quantitative Imaging Biomarker Alliance: A Paradigm for Validating Quantitative Ultrasound Methods, International Symposium on Ultrasonic Imaging and Tissue Characterization, Arlington, Va., 2013.

Hall TJ, Quantitative Imaging in Ultrasound: Elasticity and Backscatter Related Measures. RSNA 2013, Course RC825A.

Posters:

Cohen-Bacrie C, Garra B, Hall TJ, et. al., QIBA Technical Committee for Shear Wave Speed (SWS) Measurement, RSNA 2012

Hall TJ, Milkowski A, Garra B, et. al., RSNA/QIBA: Shear Wave Speed as a Biomarker for Liver Fibrosis Staging, RSNA 2013, poster.

QIBA Ultrasound Shear Wave Speed - Clinical Applications & Biological Targets Subcommittee - Est: May 2012

Co-Chairs:

- Anthony Samir, MD, MPH - (Massachusetts General Hospital)
- David O. Cosgrove, MD - (Imperial College, School of Medicine/Hammersmith Hospital, London)
- Claude Cohen-Bacrie, MS - (Supersonic Imagine [SSI], Aix-en-Provence, France)

Purpose: To provide the necessary clinical perspective and data to inform development of QIBA profiles for the clinical application of sheer wave elastography for liver fibrosis staging.

Activities and Deliverables

- A UPICT protocol, based on the protocol used at Massachusetts General Hospital, is in Version 2. It is under review by industry to provide device-specific data for the UPICT protocol.
- A draft case report form has been developed and is currently in Version 5. The form covers confounders, measurements, and reference standard pathology.
- Online research registry. The draft case report form has been uploaded to REDCAP (Research Electronic Data Capture) as an online research system and has been made available to other QIBA group members and will be available to the research community later in 2014.
- Images have been uploaded into QIDW.
- A survey has been created, intended for distribution among hepatologists, to help establish clinical confounders that would likely affect SWS assessments of liver fibrosis stage. That information will be incorporated into the QIBA Profile.

QIDW - Quantitative Imaging Data Warehouse

QIBA - RIC Informatics Task Force - Est: July 2011

Chair: Katherine P. Andriole, PhD

Purpose:
To address the informatics needs of the QIBA research community, and to provide recommendations to accelerate development of industry tools to support the standardization of, and infrastructure for, quantitative imaging. In particular, to develop and implement a quantitative imaging data warehouse (QIDW).

The task force is a joint effort between QIBA and the RSNA Radiology Informatics Committee. The purpose of the QIDW is to facilitate data and algorithm sharing, and research collaboration to promote the development and adoption of quantitative imaging by the research and clinical radiology communities.

Activities and Deliverables

QIDW has been in development and pilot testing since January 2012. It officially launched as of May 15, 2013. https://qidw.rsna.org/

The QIDW currently consists of 11 communities with a total of 110 users and more than 46,000 image uploads and has been used internationally by biomedical imaging, clinician and industry research collaborators. QIDW is currently restricted to QIBA members, but plans include providing open access to the public. Initially the QIDW has been used for phantom images and digital reference objects only, but clinical images are now being uploaded for research activities. QIDW User Agreement, Data Upload and User Access forms have been formalized. Data curation services will be provided for clinical images. Increased functionality for image data, metadata, and algorithm storage are in development, as well as analysis resources for the quantitative imaging research community.

Meeting Presentations:

"Quantitative Imaging: A Revolution in Evolution," RSNA in Association with SIIM, 2012, 2013, 2014 annual meetings.

"The Role of Informatics in Quantitative Imaging," RSNA in Association with AAPM, 2012, 2013, 2014 annual meetings.

"Introduction to Quantitative Imaging," SIIM 2013 Annual Meeting.

Funded projects

Round 1 of funding (2011-2012):

Project Title: Groundwork for QIBA image reference database - QIBA Image Reference

PI/ Institution: Gudrun Zahlmann, PhD (Roche); Rick Avila, MS (Kitware)

Status: A White Paper was created to guide the formation of the QIBA-RIC Task Force.

Ad Hoc Sustainability Task Force

QIBA Ad Hoc Sustainability Task Force - Est: November, 2012

Chair: Morgan Nields - INTIO, Inc.

- Scott Wollenweber, Chair of Subcommittee on Profile Compliance Accreditation

Purpose: To identify and explore ways to generate funds to support the development of additional Profiles and establish a revenue stream for ongoing groundwork of the QIBA Technical Committees.

Activities and Deliverables

The Sustainability Task Force produced a report listing several possibilities for generating revenue, including:

- Developing and selling standards
- Accreditation/compliance certification
- Phantom and digital reference object (DRO) Development
- Consulting services
- Collaborative outreach
- Access to datasets

The Subcommittee on Profile Compliance Accreditation further evaluated the possibility of generating revenue from accreditation activities and produced a report recommending that RSNA/QIBA explore this possibility with other organizations that already have accreditation programs, such as the American College of Radiology.

Collaborations:

Discussions with Technical Assessment Committee (TAC) of AAPM, regarding potential role of TAC in Profile Compliance Accreditation.

Metrology

QIBA Metrology Working Group - Est: April, 2012

Co-Chairs:

- Nancy Obuchowski, PhD - (Cleveland Clinic)
- Larry G. Kessler, ScD - (University of Washington)
- David L. Raunig, PhD - (ICON Medical Imaging)

Purpose:

- Recommend and define terminology to use in describing imaging biomarkers and their technical performance
- Define technical performance metrics and methodologies needed to measure and report technical performance of a QIB
- Provide a framework for QIB algorithm comparisons

Activities and Deliverables

Over the course of two years, three subgroups met via multiple conference calls and two workshops to discuss and refine recommendations. The three subgroups then evolved into five writing groups to create manuscripts for a special edition of *Statistical Methods in Medical Research*. The five papers are available on the QIBA website: https://www.rsna.org/research/quantitative-imaging-biomarkers-alliance/metrology-papers.

These papers, listed here, form an important resource for the quantitative imaging community.

Kessler, LG, et. al., The Emerging Science of Quantitative Imaging Biomarkers Terminology and Definitions for Scientific Studies and Regulatory Submissions; *Stat Methods Med Res 0962280214537333, first published on June 11, 2014 as doi:10.1177/0962280214537333*

Raunig, DL, et. al., Quantitative Imaging Biomarkers: A Review of Statistical Methods for Technical Performance Assessment; Stat Methods Med Res *0962280214537344, first published on June 11, 2014 as doi:10.1177/0962280214537344*

Obuchowski, NA, et. al., Quantitative Imaging Biomarkers: A Review of Statistical Methods for Computer Algorithm Comparisons; Stat Methods Med Res *0962280214537390, first published on June 11, 2014 as doi:10.1177/0962280214537390*

Obuchowski, NA, et. al., Statistical Issues in the Comparison of Quantitative Imaging Biomarker Algorithms Using Pulmonary Nodule Volume as an Example; Stat Methods Med Res *0962280214537392, first published on June 11, 2014 as doi:10.1177/0962280214537392*

Huang, EP, et. al., Meta-analysis of the Technical Performance of an Imaging Procedure: Guidelines and Statistical Methodology; Stat Methods Med Res *0962280214537394, first published on May 28, 2014 as doi:10.1177/0962280214537394*

Future Plans

During the first few years of QIBA much committee discussion focused necessarily on developing concepts, procedures, and policies for QIBA Committee activity and deliverables.

Stakeholders set out to create and agree on a shared vision, strategic plan and operational plans to accomplish the goals of QIBA.

Now that such a foundation has been established, QIBA Committees will focus on more expeditiously producing new, additional QIBA Profiles. Also, the first few Profiles that were written will be revised in light of better appreciation of the sources of variability in image quantification and improved agreement about how to express QIBA Claims and structure QIBA Profiles.

We also plan to emphasize dissemination and implementation of QIBA Profiles into clinical trials or into clinical practice, depending on which is more relevant for a given Profile. Processes for determining and publishing compliance with QIBA Profiles are another area of active work. We are also working to enhance and expand the Quantitative Imaging Data Warehouse to make it a more valuable research resource to the imaging community.

Furthermore, there is international interest in quantitative imaging biomarkers, and formal expansion of QIBA with European and Asian professional radiology organizations is under way. In summary QIBA is working to move the "thought needle" more towards quantitative imaging, to make clinical imaging less of an art and more of a science.

All QIBA Committees are open to all interested persons. To participate, or to learn more, contact RSNA staff at QIBA@rsna.org. We look forward to hearing from you!

QIBA Activities

RSNA Receives Additional Funding for QIBA

An additional year of funding was awarded to RSNA by the National Institute of Biomedical Imaging and Bioengineering (NIBIB) for QIBA activities. This is the fourth consecutive year that NIBIB has funded QIBA activities. This new $1.27 million award will go towards supporting QIBA research projects, including further development of a Quantitative Imaging Data Warehouse, and the QIBA Annual meeting.

Mark Your Calendar! **RSNA 2014**

QIBA Technical Committees - Working Meeting at RSNA 2014
Chicago, McCormick Place
Wednesday, December 3rd | 2:30pm – 5:00pm

The ongoing work of the Technical Committees is posted on the QIBA wiki page: http://qibawiki.rsna.org. New participants in QIBA Technical Committees are always welcome; please contact QIBA@rsna.org for more information.

QIBA in the Literature

Articles are divided into two categories:

1. *Articles that are generated by Quantitative Imaging Biomarkers Alliance (QIBA) research teams*
2. *Articles that reference QIBA*

These are articles published by QIBA members, or ones that relate to a research project undertaken by QIBA members that may have received special recognition. New submissions are welcome and may be directed to QIBA@rsna.org.