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

Contact us
Comments & suggestions welcome

Daniel C. Sullivan, MD
RSNA Science Advisor

IN MY OPINION

What Exactly are QIBA Profiles and Why are They Important?

By ANDREW J. BUCKLER, MS

Enhanced imaging techniques have made medical imaging an essential component of healthcare. An increasing number of quantitative analysis approaches ranging from morphological to functional measurements have been developed to create objective and quantitative readouts. Quantitative imaging has the potential to improve the value of diagnostic testing and enhance clinical productivity.

While the imaging industry is transitioning to developing devices that are optimized for quantitative imaging, performance

expectations, particularly the rigor with which performance is statistically characterized, are higher with quantitative than with qualitative imaging. Moreover, a standardized interpretation of the results is necessary in order that the measurements be understood as clinically significant. Individual companies are constrained by their business models to pursue only activities that can be justified in the short-term with respect to that company. Furthermore, individual manufacturers do not commonly address the need for cross-vendor standardization.

A QIBA* Profile is a document that describes how to achieve a specific performance claim when targets (inanimate or living) are imaged under specific conditions (including, but not limited to, imaging system requirements and protocols). It organizes and records relevant information from the published literature as well as results of the collaborative work by QIBA participants.

A Profile consists of one or more "Claims" and associated "Details."

- Claims tell a user what can be accomplished by following the Profile
- Details tell a vendor what must be implemented in their product before they can declare compliance with the Profile, and tell a user the necessary procedures for achieving the Claim(s).

As such, a Profile serves as both a documented standard as well as a basis for the cooperation of stakeholders in assessing performance.

With such standardization in place, it would be possible to perform multiple studies and pursue objectives that would not be feasible for individual sponsors alone, be they biopharmaceutical companies seeking to develop drugs or hardware/software companies seeking to develop solutions for clinical care. Although many stakeholders are interested in this goal, none can accomplish it alone. The goal of QIBA is to establish processes and Profiles (standards documents) that will lead to acceptance of quantitative imaging applications by the imaging community.

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. 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 utilization.

QIBA profiles are available for public comment. Please visit the QIBA WIKI at qibawiki.rsna.org/index.php?title=Work_Product_for_Review

References:
*QIBA = Quantitative Imaging Biomarkers Alliance

Andrew J. Buckler, MS, has over 25 years of experience in the device manufacturing industry. Mr. Buckler serves as Program Director of QIBA, scientific advisor to the Foundation for the National Institutes of Health (FNIH) in connection with the qualification of volumetric CT and quantitative FDG-PET for regulatory decision making in clinical trials, and as a PI for QI-Bench, a National institute of Standards and Technology (NIST)-supported program to develop informatics services used to assess performance of quantitative imaging biomarkers.

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ANALYSIS TOOLS & TECHNIQUES

Developing an Informatics and Database Infrastructure for Proficiency Testing of Quantitative Imaging Algorithms

By ALDEN DIMA, MS

Imaging biomarkers are intended for use in both patient care and in clinical trials of new therapies. Although both qualitative and quantitative biomarkers are useful, the need for quantitative biomarkers is currently emphasized by the medical community. Quantitative imaging should allow for precise measurement of clinically relevant features when applied and interpreted in a consistent manner. However, the use of imaging biomarkers is hindered by a lack of a standardized interpretation. This in turn, is exacerbated by large measurement variabilities under differing use contexts, imaging modalities and platforms.

The purpose of the QI-Bench project[1] is to collect evidence supporting the implementation of imaging biomarkers and to ensure that sufficient, quality data are generated to enable the responsible use of these new tools in clinical settings. The project proposes an overall architecture based on open-source software in which needed functionality is divided among five applications: Specify, Formulate, Execute, Analyze, and Package.

- **Specify**[2] will allow users to specify context for use and assay methods using consensus terms. It will be a Protégé[3], BioPortal[4], and Ruby-on-Rails-based[5] Profile Editor application that builds the internal representation to specify quantitative imaging biomarkers and assay methods used downstream.

- **Formulate**[6] will allow for the assembly of applicable reference data sets that include both imaging and non-imaging clinical data. It will form a Linked Data Archive with an extension to clinical data and is the part of the project that is most closely associated with existing caBIG tools[7], comprising such capabilities as caB2B, caIntegrator, the PODS data elements, and an NBIA connector into Kitware's MIDAS image archiving system[8].

- **Execute**[9] will enable the composition and iteration of batch analyses on reference data and accumulation of quantitative readouts for analysis. It serves as a Reference Data Set Manager and a Batch Analysis Service and results in annotation and image mark-up across large data sets. The Execute application will be implemented using Kitware's MIDAS and BatchMake[10] software, as well as the Condor grid[11].

- **Analyze**[12] will characterize a biomarker method relative to its intended use by applying existing analysis tools and allowing those tools to be extended as needed. Analyze is most closely associated with the Measurement Variability Toolkit portion of the Algorithm Validation Toolkit[13] as well as the ideas being discussed for a library of reference statistical analysis methods.

- **Package**[14] will allow users to compile evidence for regulatory filings and enable a standards-based transfer to regulatory agencies. This portion of the project is most closely associated with the Clinical Data Interchange Standards Consortium (CDISC) and the U.S. Food and Drug Administration (FDA) and would generate data in the study data tabulation model (SDTM) for biomarker qualification in CDER[15] and test approval/clearance in CDRH[16], as well as corresponding worldwide agencies.

These applications would be available in two forms: as web services linking to the databases on the project server *dev.bbmsc.com*; and as a local installation for more sophisticated users.

Our approach is to run two parallel core activities. The first starts with use case analysis and proceeds to requirements and systems engineering; the other creates demonstrators that extend existing system capabilities. A shared activity is an inventory of current

system capabilities and a gap analysis. In the fall of 2011, we will initiate an iterative development process to create the services. We will report our progress via semi-annual reports that will be available in February and August.

References:

[1] QI-Bench, www.qi-bench.org/wiki

[2] QI-Bench "Specify" Scope Description, June 2011, Rev 0.1

[3] The Protégé Ontology Editor and Knowledge Acquisition System, protege.stanford.edu

[4] Welcome to NCBO BioPortal, bioportal.bioontology.org

[5] Ruby on Rails, rubyonrails.org

[6] QI-Bench "Formulate" Scope Description, June 2011, Rev 0.1

[7] Cancer Biomedical Informatics Grid (caBIG), cabig.nci.nih.gov

[8] MIDAS, www.kitware.com/products/midas.html

[9] QI-Bench "Execute" Scope Description, June 2011, Rev 0.1

[10] BatchMake, batchmake.org

[11] Condor: High Throughput Computing, www.cs.wisc.edu/condor

[12] QI-Bench "Analyze" Scope Description, June 2011, Rev 0.1

[13] Algorithm Validation Toolkit, cabig.nci.nih.gov/tools/AVT

[14] QI-Bench "Package" Scope Description, June 2011, Rev 0.1

[15] Drugs, www.fda.gov/Drugs/default.htm

[16] Medical Devices, www.fda.gov/MedicalDevices/default.htm

Alden Dima, MS, is a Computer Scientist in the Software and Systems Division (SSD) of the National Institute of Standards and Technology (NIST) and is the project lead for Medical Imaging within NIST/SSD.

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FOCUS ON

RSNA 2011: QIBA Meetings and Activities

MARK YOUR CALENDAR: RSNA 2011

Quantitative Imaging/Imaging Biomarkers Special Interest Session
Monday, November 28, 4:30 PM - 6:00 PM

QIBA Technical Committees Working Meeting
Wednesday, November 30, 3:00 PM - 5:00 PM

VISIT THE LAKESIDE LEARNING CENTER (HALL E)
The Quantitative Imaging Reading Room
RSNA 2011 will once again feature *The Quantitative Imaging Reading Room*. This educational showcase will provide visual and experiential exposure to quantitative imaging and biomarkers through exhibitor products that integrate quantitative analysis into the image interpretation process. Participants can learn through hands-on exhibits featuring informational posters, computer-based demonstrations and Meet the Expert presentations scheduled throughout the week.

QIBA Activities
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.

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QI/IMAGING BIOMARKERS IN THE LITERATURE

PubMed Search on: "What Exactly are QIBA Profiles and Why are They Important?"

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: "What Exactly are QIBA Profiles and Why are They Important?" here.

For more information, please visit the QIBA WIKI:
What are Profiles and Protocols?

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