AAPM QI Symposium – July 2014

Quantitative Imaging Initiatives: Why, Who, What, and How?

RSNA Quantitative Imaging Biomarkers Alliance

Edward F. Jackson, PhD
Departments of Medical Physics, Radiology, and Human Oncology
University of Wisconsin – Madison

Premise and RSNA Perspective

- Premise: Variation in clinical practice results in poorer outcomes and higher costs.
- RSNA Perspective: Extracting objective, quantitative results from imaging studies will improve the value of imaging in clinical practice.

2

RSNA QIBA

- Started in 2007
- Mission
  - Improve the value and practicality of quantitative imaging biomarkers by reducing variability across devices, patients, and time.
  - "Industrialize imaging biomarkers"
- Focused Specifically on Technical Performance

3

RSNA QIBA Approach

- Four Components to QIBA Approach:
  - Identify sources of bias and variance in quantitative results
  - Develop potential solutions
  - Test solutions
  - Promulgate solutions
- Accomplished by developing "QIBA Profiles" and "QIBA Protocols"

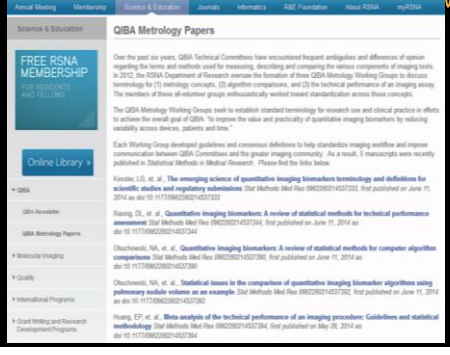
4

RSNA QIBA Approach

- Profile
  - A document that describes a specific performance claim and how it can be achieved.
  - Claims: tell a user what can be accomplished by following the Profile.
  - Details: tell a vendor what must be implemented in their product; and tell a user what procedures are necessary.
- Protocol
  - Describes how clinical trial subjects or patients should be imaged so as to achieve reproducible quantitative endpoints when those tests are performed utilizing systems that meet the specific performance claims stated in the QIBA Profiles.

5

RSNA Metrology Workgroups



Informs claim development

QIBA Claim Template

- List Biomarker Measurand(s)
- Specify: Cross-sectional *vs*. Longitudinal measurement
- List Indices:
  - Bias
  - Precision
    - Test-retest Repeatability (Repeatability coefficient [RC])
    - Reproducibility (Reproducibility coefficient [RDC]; Intraclass Correlation Coefficient [ICC]; Concordant Correlation Coefficient [CCC])
      - Specify conditions, *e.g.*,
        - Measuring system variability (hardware & software)
        - Site variability
        - Operator variability (intra- or inter-reader)
- Clinical Context

7

QIBA Claim Example (DW-MRI)

Biomarker measurand: *in vivo* tissue water mobility, commonly referred to as the apparent diffusion coefficient (ADC)

- Cross-sectional measurement: Disease state determination via absolute ADC value (thresholds)
  - Bias: When measuring an ice-water phantom at isocenter, the ADC measurement will exhibit no more than a 5% bias from the reference value of 1.1 x 10^{-9} m^2/s
  - Precision:
    - Repeatability: 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)
- Longitudinal measurement: measurement of ADC as an indicator of treatment response …

DRAFT claim statement

8

Profile Template

Table of Contents

Profile Template

Table of Contents

Profile Template

Table of Contents

Open Issues: ... 3
Closed Issues: ... 3
1. Executive Summary ... 4
2. Clinical Context and Claims ... 4
  Utilities and Endpoints for Clinical Trials ... 4
  Claim: [short description] ... 4
  Claim: [repeat for as many distinct claims as being made] ... 4
3. Profile Activities ... 5
  3.1. Subject Handling ... 7
    3.1.1 Timing Relative to Index Intervention Activity ... 7
    3.1.2 Timing Relative to Confounding Activities ... 8
    3.1.3 Contrast Preparation and Administration ... 8
    3.1.4 Subject Positioning ... 9
    3.1.5 Instructions to Subject During Acquisition ... 9
    3.1.6 Timing/Triggers ... 9
  3.2. Image Data Acquisition ... 10
  3.3. Image Data Reconstruction ... 10
  3.4. Image Analysis ... 11
4. Compliance Procedures ... 11
  4.x. Performance Assessment: <Parameter X> ... 12
  4.y. Performance Assessment: <Parameter Y> ... 12
References ... 13
Appendices ... 14
  Appendix A: Acknowledgements and Attributions ... 14
  Appendix B: Background Information ... 14
  Appendix C: Conventions and Definitions ... 14
  Appendix D: Model-specific Instructions and Parameters ... 15

Profile Template

Table of Contents

Open Issues: ... 3
Closed Issues: ... 3
1. Executive Summary ... 4
2. Clinical Context and Claims ... 4
  Utilities and Endpoints for Clinical Trials ... 4
  Claim: [short description] ... 4
  Claim: [repeat for as many distinct claims as being made] ... 4
3. Profile Activities ... 5
  3.1. Subject Handling ... 7
    3.1.1 Timing Relative to Index Intervention Activity ... 7
    3.1.2 Timing Relative to Confounding Activities ... 8
    3.1.3 Contrast Preparation and Administration ... 8
    3.1.4 Subject Positioning ... 9
    3.1.5 Instructions to Subject During Acquisition ... 9
    3.1.6 Timing/Triggers ... 9
  3.2. Image Data Acquisition ... 10
  3.3. Image Data Reconstruction ... 10
  3.4. Image Analysis ... 11
4. Compliance Procedures ... 11
  4.x. Performance Assessment: <Parameter X> ... 12
  4.y. Performance Assessment: <Parameter Y> ... 12
References ... 13
Appendices ... 14
  Appendix A: Acknowledgements and Attributions ... 14
  Appendix B: Background Information ... 14
  Appendix C: Conventions and Definitions ... 14
  Appendix D: Model-specific Instructions and Parameters ... 15

Profile Template

Table of Contents

Profile Review and Dissemination

Profile stages:

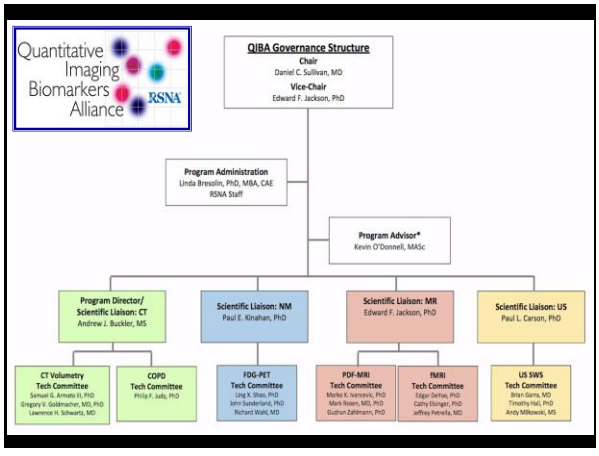
- Development Phase
  - Writing Group formation, literature review, groundwork projects (if needed)
- Version for Public Comment
  - In the Writing Group's opinion, the Profile describes the key factors that affect the claim and proposes recommended procedures that address the factors.
- Publicly Reviewed Version
  - Writing Group has formally addressed each issue raised during the public comment. All changes are documented.
- Technically Confirmed Version
  - Profile details have been implemented in a test setting and each participating system and person successfully met the performance specifications.

14

Who Does All The Work?

- Profiles and Protocols are developed within six Technical Committees, organized by modality (CT, NM/PET, MR, US).
- Administrative Support: RSNA HQ staff
- Everything else: Primarily volunteer efforts. Anyone who is interested is welcome (and encouraged) to join!
- http://www.rsna.org/qiba

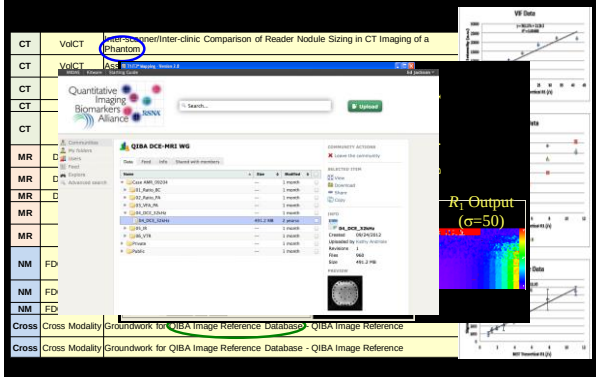
15



Groundwork Projects

- Funding for groundwork projects required for Profile development has been provided by two consecutive 2-year contracts from NIBIB to RSNA.
- Three rounds of groundwork project awards have been provided thus far, with a 4th round to start in September 2014.

RSNA QIBA Projects – Round 1



RSNA QIBA Projects – Round 2

CT	VolCT	Extension of Assessing Mea Data Sets: Variability Under
CT	VolCT	Extension of Assessing Mea Data Sets: Variability Under
CT	VolCT	Comparative Study of Algori Lesions: Assessing the Effec Variability
CT	COPD	Impact of Dose Saving Proto Asthma
MR	DCE-MRI	Test-Retest Evaluation of Repe
MR	fMRI	Validation of Breath Hold Ta Responsiveness and Calibra Reproducibility
NM	FDG-PET/CT	Personnel Support for FDG-
NM	FDG-PET/CT	Evaluation of the Variability i Treatment Response Across
NM	FDG-PET/CT	PERCIST Validation
NM	FDG-PET/CT	Evaluation of FDG-PET SU

ACRIN AMERICAN COLLEGE OF RADIOLOGY IMAGING NETWORK

Quantitative Imaging Biomarkers Alliance RSNA

AMERICAN COLLEGE OF RADIOLOGY IMAGING NETWORK and QUANTITATIVE IMAGING BIOMARKERS ALLIANCE

ACRIN 6701

Repeatability Assessment of Quantitative DCE-MRI and DWI: A Multicenter Study of Functional Imaging Standardization in the Prostate

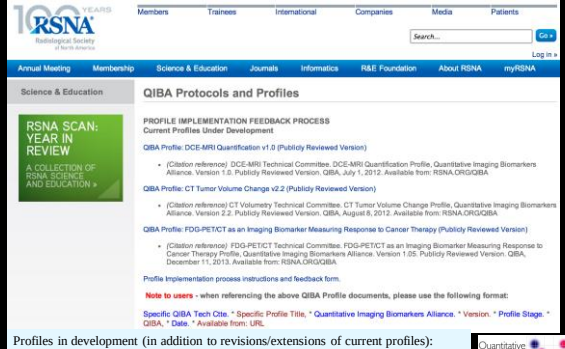
Primary goals and objectives – *in vivo* test/retest protocol

– 1) Determine the test-retest performance, as assessed by the coefficient of variation, of the median pixel values of K^{trans} and $IAUGC_{be}$, using the whole prostate as the target "tumor".

RSNA QIBA Projects – Round 3

CT	VolCT	Second 3A Statistical and Image Processing Analysis	Andrew Buckler, MS Buckler Biomedical Sciences LLC
CT	VolCT	Phantoms for CT Volumetry of Hepatic and Nodal Metastasis	Binsheng Zhao, DSc Columbia
MR	PDF-MRI	DW-MRI ADC Phantom	Michael Boss, PhD Boulder/NIST
MR	PDF-MRI	Software Development for Analysis of QIBA DW-MRI Phantom Data	Thomas Chenevert, PhD University of Michigan
MR	PDF-MRI	Development of a Tool to Evaluate Software Using Artificial DCE-MRI Data and Statistical Analysis	Hendrik Laue, PhD Fraunhofer MEVIS, Germany
MR	PDF-MRI	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	Thorsten Persigehl, MD University Hospital Cologne, Germany
MR	fMRI	fMRI Digital Reference Objects for Profile Development and Verification	Edgar DeYoe, PhD Medical College of Wisconsin
NM	FDG-PET/CT	FDG-PET/CT Profile Field Test	Timothy Turkington, PhD Duke University
NM	FDG-PET/CT	FDG-PET/CT Digital Reference Object (DRO) Extension	Paul Kinahan, PhD University of Washington
US	US-SWS	Numerical Simulation of Shear Wave Speed Measurements in the Liver	Mark Palmeri, MD, PhD Duke University
US	US-SWS	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	Anthony Samir, MD, MPH Massachusetts General Hospital
Cross	Cross	Design and Statistical Analysis of Studies of Compliancy with QIBA Claims	Nancy Obuchowski, PhD Cleveland Clinic Foundation

Current QIBA Profiles



Profiles in development (in addition to revisions/extensions of current profiles):

- DWI/ADC
- fMRI
- US SWS

Quantitative Imaging Biomarkers Alliance RSNA

Profile Template

Table of Contents

Acknowledgments

- Daniel Sullivan, MD - Chair, RSNA QIBA
- Linda Bresolin, PhD, MBA and all RSNA HQ staff members who support the QIBA efforts
- RSNA QIBA DCE- / PDF-MRI Technical Committee Co-Chairs & Members
- Daniel Barboriak, MD - Digital Reference Object (DCE)
- Mark Rosen, MD, PhD - ACRIN 6701 Protocol
- NIBIB / RSNA Contract HHSN268201000050C

http://www.rsna.org/qiba

23