QIBA Annual Meeting

May 17, 2017

Welcome and Overview

• Welcome
• Agenda and Logistics
• Overview and Current Status
Current Status of QIBA*

- Over 1,060 individuals have joined the QIBA effort, representing all major stakeholders in the quantitative imaging initiative:
  - Radiologists
  - Imaging scientists
  - Pharmaceutical companies
  - Imaging device companies
  - Imaging informatics and other software companies
  - Government agencies
  - Professional societies
  - Clinical trialists and clinicians
  - Statisticians and metrologists
- More than 300 individuals from over 100 companies, 18 from the FDA, 44 from other agencies (excluding FDA)
- Vast majority of stakeholder efforts are voluntary

*As of 11/22/2016
Selected Recent Activities

Continued Maturation and Recent Milestones

• Ongoing Claim Guidance and Profile Template improvements to address the continued evolution in statistical rigor

• First Profile advancement to Technically Confirmed stage

• QIBA featured by Cancer Moonshot initiative

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**Claims:**

"95% probability that measured change -25% to +30% encompasses the true tumor volume change…"

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**Profile Activities:**

**Actor Table**

- Acquisition Device
- Measurement Software
- Radiologist
- Activity Definitions
  - Product Validation
  - Calibration / QA
  - Patient Preparation
  - Image Acquisition / Recon
  - Post-Processing
  - Analysis / Measurement

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**Equipment Vendor View**

- Why do you want me to do this?
  - Which of my products are affected?
- What do I have to implement?
  - (requirement checklists: features, capabilities, performance targets)
- How will I be tested?
### Profile Stages

<table>
<thead>
<tr>
<th>Stage Name</th>
<th>Stage Meaning</th>
<th>Stage Criteria</th>
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</table>
| Stage 1 Draft for Public Comment | Key factors affecting the claim(s) are described and procedures address each/most of the factors. | • Open issues clearly listed  
• Some groundwork may be ongoing  
• Actor requirements clear & justified |
| Stage 2 Consensus   | Consensus has been reached and Profile is ready for feasibility testing.      | • Text reasonably stable  
• Public comments addressed  
• Open issues mostly resolved |
| Stage 3 Technically Confirmed | The Profile is practical to understand and implement, and is ready for claim testing. | • Text stable  
• Open issues resolved  
• Procedures implemented at test sites & multiple vendor platforms (≥2 each) |
| Stage 4 Claim Confirmed | Claimed performance can be achieved. The Profile is ready for clinical testing. | • Performance measured at test site  
• Profile Claims achieved at limited number of sites / vendors (≥2 each) |
| Stage 5 Clinically Confirmed | Claimed performance will typically be achieved. | • Profile Claims achieved in clinical use at multiple sites |

• **19 Profiles total** (4 CT, 3 NM, 9 MR, 3 US)

• **Technically Confirmed Stage:**
  - FDG-PET/CT SUV as an Imaging Biomarker for Measuring Response to Cancer Therapy (v1.05)*

• **Publicly Reviewed (Consensus) Stage and Posted:**
  - CT Tumor Volume Change (v2.2) for tumor response*
  - DCE-MRI Quantification (v1.0) for tumor response

• **In Public Comment and Consensus Development Stage:**
  - CT: Lung Nodule Volume Assessment and Monitoring in Low Dose CT Screening Quantification
  - SPECT: Quantifying Dopamine Transporters with 123-Iodine labeled Ioflupane in Neurodegenerative Disease
  - DW-MRI for tumor response

*Highlighted on Cancer Moonshot website

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• **In Final Stage of Development for Public Comment Stage:**
  - PET amyloid for Alzheimer’s Disease
  - fMRI for pre-surgical planning
  - MR elastography for liver fibrosis
  - Ultrasound shear wave speed for liver fibrosis
  - CT lung densitometry for COPD

• **In Development:**
  - CT tumor volume change for liver lesions
  - MR proton density fat fraction (PDFF) for liver disease
  - Dynamic susceptibility contrast (DSC)-MRI for perfusion assessment in brain
  - Revised DCE-MRI to address 3T and parallel imaging
  - MR diffusion tensor imaging (DTI) for traumatic brain injury
  - Arterial spin labeling (ASL) MR – collaboration with EIBALL
  - Ultrasound volume flow for perfusion studies
  - Contrast-enhanced ultrasound (CEUS) for perfusion studies

• Also: FDG-PET/CT Protocol (with summary published in JNM in April 2015)
QIBA Metrology Working Group

- Five manuscripts published in *Statistical Methods for Medical Research* in 2014.
- One manuscript published in *Radiology* in 2015.
- All available at www.rsna.org/qiba.

QIBA Deliverables*

<table>
<thead>
<tr>
<th>Profiles* &amp; Protocols</th>
<th>Manuscripts</th>
<th>Presentations</th>
<th>Posters</th>
<th>Physical Phantoms</th>
<th>Digital Reference Objects</th>
<th>Software Apps</th>
<th>Datasets</th>
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</thead>
<tbody>
<tr>
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<td>42</td>
<td>4</td>
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</tbody>
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*Publicly reviewed stage

Number of Publications/Book Chapters that Cite QIBA: 27
QIDW: 423 users and 17 communities**

*As of May 10, 2017
**As of November 22, 2016

NIBIB Contracts

NIBIB Funding

- Summary of NIBIB-funded groundwork projects (~$625K per round):
  - Round 1 (2011-12): N=16 – completed
  - Round 2 (2012-13): N=12 – completed
  - Round 6 (2016-17): N=13 – ongoing
QIBA Groundwork Projects

QIB Implementation and Qualification

• Data acquisition* => Physical phantoms & datasets
  • Application specific

• Data analysis* => Synthetic phantoms & datasets
  • Application specific “digital reference objects“ or DROs

• Qualification => “Fit for purpose“ <= clinical trials

*QIBA groundwork projects funded by 3 contracts from NIH

QIBA Phantoms & Datasets

• Physical Phantoms
  • Volumetric CT Liver Phantom (arterial/portal venous phase)
  • DCE-MRI Phantom and analysis software
  • DWI ADC Phantom and analysis software
  • DSC-MRI Phantom (in development; target release Q2/2017)
  • Shear Wave Speed Phantoms (varying viscoelastic properties) – for both US SWS & MRE

• Digital Reference Objects (Synthetic Phantoms)
  • Volumetric CT DRO (Liver, Lung, Kidney)
  • DCE-MRI DRO ($T_1$ mapping and $K^{trans}$, $v_e$) and analysis software
  • DWI ADC DRO
  • DSC-MRI DRO (in development; target release Q3/2017)
  • fMRI DROs (motor and language mapping)
  • PET SUV DRO
  • SPECT DRO ($^{23}$I dopamine transporter, DaTscan/Ioflupane; in development; Q3/2017)

• Datasets on QIDW
### Challenges

**Maintaining Momentum** => timely release of relevant deliverables
- Maintain focus on “industrializing QIBs” vs. academic desire for “perfecting QIBs”
- Driving completion of Profiles and Conformance Procedures while relevant

**Profile “Life Cycle” and Prioritizations**
- Continuous monitoring of Profile portfolio
- Decisions re: maintenance, revision, sun-setting

**Conformance Processes**
- Availability of required phantoms, software, and data sets (w/meta data)
- Well-defined feasibility test procedures (parameter space and pass criteria) => “check lists”
- QIDW population of appropriate DROs and data sets, as well as analytics, to facilitate conformance validation

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### Field Testing of Profiles

- Realistic goal(s) of field testing of a Technically Confirmed Profile => Claim Confirmed
- Identification of opportunities for collaborations, e.g., ECOG/ACRIN, etc.

**International Efforts**
- Harmonization of efforts => creating opportunities for synergism

**QIDW**
- Must ensure that all relevant QIBA contract deliverables are available
- Potential enabling role in conformance testing => need for procedures, data, software

**Sustainability**
- Continued success in achieving well-defined, relevant goals => timely deliverables
- Diversification of revenue sources, beyond NIBIB
- Conformance processes are key deliverables
NIBIB Contract Status

- In final year of third 2-year contract
- No current option for additional contract
- Financial impact: Loss of ~$1.2M NIBIB funds for FY17-18
- Increased support from RSNA Board ($207K) for FY17-18
- Bottom line: FY17-18 available funding about one-half of FY16-17 level
- Impact: Groundwork projects (no funding) and decreased funding for consultant positions, meetings, travel, QIDW, posters/miscellaneous.
- Maintaining current level of support for RSNA staff supporting QIBA, WebEx support.