QIBA AM Meeting Agenda

- General Meeting Welcome and Logistics  
  - Linda Bresolin and Fiona Miller
- Current Status of QIBA

QIBA AM – June 12, 2019

QIBA Current Status

Edward F. Jackson, PhD  
Chair, RSNA QIBA  
Professor and Chair, Department of Medical Physics  
Professor of Radiology and Human Oncology
19 Biomarker Committees
4 Task Forces (TFs)

14-August-2018

QIBA Deliverables (1)

Imaging Metrology – Consistent with International Vocabulary of Metrology (VIM)

- Five manuscripts in *Statistical Methods for Medical Research* (2015)*
- One manuscript in *Radiology* (Sullivan, et al. 2015)*
- One manuscript in *Journal of the National Cancer Institute***

- Robust statistical framework for:
  - Development of cross-sectional and longitudinal claims
  - Conformance assessment with profile specifications
  - Study design for clinical trials using QI biomarkers

- Developing statistical framework for:
  - Multi-parametric measurands (needed for radiomics and other applications where a single measurand is inappropriate or insufficient)

*Available at www.rsna.org/qiba  ** Obuchowski, et al. Statistical Considerations for Planning Clinical Trials with Quantitative Imaging Biomarkers, 2019
QIBA Deliverables (2)

Profiles (20 total; 5 CT, 3 NM, 9 MR, 3 US*)

*As of 4/26/2019

Current Profile Status
(As of 4/8/2019)

20 Profiles (5 CT, 3 NM, 9 MR with 1 on hold, 3 US)

• Technically Confirmed Stage:
  – NM: FDG-PET/CT SUV as an Imaging Biomarker for Measuring Response to Cancer Therapy
  – CT: Tumor Volume Change for Advanced Disease

• Publicly Reviewed (Consensus) Stage:
  – CT: Lung Nodule Volume Assessment & Monitoring in Low Dose CT Screening Quantification
  – NM: Quantifying Dopamine Transporters with $^{123}$Iodine-labeled Ioflupane in Neurodegenerative Disease (SPECT)
  – NM: $^{18}$F-labeled PET Tracers Targeting Amyloid as an Imaging Biomarker
  – MR: MR Elastography of the Liver
  – MR: DCE-MRI Quantification (v1.0) for tumor response

• In Public Comment and Resolution Stage:
  – MR: DW-MRI for tumor response
  – MR: fMRI for pre-surgical planning
  – CT: Atherosclerosis biomarkers assessment

For details: qibawiki.rsna.org
Current Profile Status  
(As of 4/8/2019)

• In Final Stage of Development for Public Comment Release:
  – CT: Lung densitometry for COPD
  – US: Ultrasound shear wave speed for liver fibrosis
  – MR: Proton density fat fraction (PDFF) for liver disease

• In Earlier Stages of Development:
  – CT: Tumor volume change for liver lesions
  – MR: Dynamic susceptibility contrast (DSC)-MRI for perfusion assessment in brain
  – MR: Diffusion tensor imaging (DTI) for traumatic brain injury (currently on hold)
  – MR: Revised DCE-MRI to address 3T and parallel imaging
  – MR: T₂ and T₁rho MSK MR for degenerative joint disease
  – US: Contrast-enhanced ultrasound (CEUS) for perfusion studies
  – US: Ultrasound volume flow for perfusion studies – collaboration with AIUM
  – MR: Arterial spin labeling (ASL) MR – collaboration with ESR EIBALL

For details: qibawiki.rsna.org

Profile Stages

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<tr>
<th>Stage Name</th>
<th>Stage Meaning</th>
<th>Stage Criteria</th>
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| Stage 1             | Draft for Public Comment                                                      | • Open issues clearly listed  
|                     |                                                                                | • Some groundwork may be ongoing  
|                     |                                                                                | • Actor requirements clear & justified  
|                     |                                                                                | • Statistical review of profile complete  |
| Stage 2             | Consensus                                                                     | • Public comments addressed  
|                     |                                                                                | • Open issues mostly resolved  
|                     |                                                                                | • Recommended procedures tested using groundwork projects  |
| Stage 3             | Technically Confirmed                                                          | • Procedures implemented at multiple test sites using equipment from multiple vendors  
|                     |                                                                                | • Conformance assessment procedures defined  |
| Stage 4             | Claim Confirmed                                                               | • Performance measured at test site  
|                     |                                                                                | • Profile Claims achieved at limited number of sites / vendors (≥2 each) |
| Stage 5             | Clinically Confirmed                                                          | • Profile Claims achieved in clinical use sites  |
QIBA Deliverables (3)

Phantoms and Analysis Software

- NIST-Traceable ADC Phantom
- Two-Phase Liver CT Volumetric Phantom
- Portal venous phase
- Arterial phase
- DCE Digital Reference Object
- FDG-PET Digital Reference Object
- CT Digital Reference Object
- DCE-MRI Digital Reference Object
- Lung
- Kidney

QIBA Phantoms & Datasets

- Physical Phantoms (with NIST and FDA)
  - Volumetric CT Liver Phantom (arterial/portal venous phase)
  - DCE-MRI Phantom and analysis software
  - DWI ADC Phantom and analysis software
  - DSC-MRI Phantom
  - Shear Wave Speed Phantoms (varying viscoelastic properties) – for both US SWS and 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
  - fMRI DROs (motor and language mapping)
  - PET SUV DRO
  - SPECT DRO ($^{123}$I dopamine transporter, DaTscan/Ioflupane)
**QIBA Phantoms & Datasets**

- **Datasets on QIDW** (qidw.rsna.org)
  - DROs
  - Example physical phantom test data
  - Software for analyses of DRO and physical phantom data
  - Conformance testing datasets for select Profiles, *e.g.*, CT Volumetry for Advanced Disease

**Adoption of QIBA Products / Concepts**

- QIBA Profiles adopted in whole or in part in clinical trials (pharma and cooperative trial groups)
- Adoption and marketing of “QIBA compliance” by some imaging core labs and software companies
- Internationalization of QIBA:
  - Active participation from individuals in South America, Europe, and Asia
  - EORTC / IMI- and Brazil-QIBA collaborations (MR DWI)
  - European Society of Radiology European Imaging Biomarker Alliance (EIBALL)
    - First formal QIBA/EIBALL collaboration: MR Arterial Spin Labeling (ASL) Task Force
  - Japan Radiological Society (Japan-QIBA)
    - Mirrored QIBA structure
    - Translation of PET/CT SUV Profile
- Prevent Cancer Foundation International Community Grants
FDA Guidance – Clinical Trial Imaging

Clinical Trial Imaging Endpoint Process Standards
Guidance for Industry

FDA Guidance re: QI

Technical Performance Assessment of Quantitative Imaging in Device Premarket Submissions
Draft Guidance for Industry and Food and Drug Administration Staff

IV. Definitions
To ensure consistency throughout this document and in premarket submissions of devices that include quantitative imaging functions, FDA encourages use of the following terminology when describing quantitative imaging functions. The terminology below is derived from Radiological Society of North America’s (RSNA) Quantitative Imaging Biomarker Alliance (QIBA), the BEST (Biomarkers, Endpoints and other Tools) glossary, the International Vocabulary of Metrology, and the IMDRF (International Medical Device Regulators Forum) “Software as a Medical Device (SaMD): Clinical Evaluation Guidance” document.
Challenges & Opportunities

• Maintaining Momentum => Timely release of deliverables
  – Development and release of profiles in a timely manner, i.e., relevance
  – Maintain focus on “industrializing QIBs” vs. academic desire for “perfecting QIBs”
  – Groundwork project funding for addressing gaps and advancing stage of profiles

• Feasibility Testing and Conformance Processes
  – Availability of required phantoms, analysis 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 cloud-based analytics, to facilitate conformance validation

Challenges & Opportunities

• 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, Alliance, NRG, etc.

• Sustainability
  – Groundwork projects, profiles, conformance processes, and imaging metrology deliverables
  – Diversification of revenue sources beyond RSNA, e.g., pharma
  – Partnership with ACR or other accreditation / certification bodies
  – Potential development of QIBA “business arm”
QIBA AM Meeting Agenda

• Plenary Session 1: Multiparametric QI Biomarker Measures
  – Nancy Obuchowski

• Panel Discussion 1: Applications of Multiparametric QI Biomarker Measures
  – Nancy Obuchowski, Moderator

QIBA AM Meeting Agenda

• Plenary Session 2: The Importance of QI in Data Science and Radiomics Initiatives
  – Brad Erickson

• Panel Discussion 2: Data Science and Radiomics Initiatives – An Opportunity (and Need) for QIBA Involvement
  – Michael Boss, Moderator
QIBA AM Meeting Agenda

• External Liaison Report and International Collaborations
  Updates – EIBALL and Japan-QIBA
  – Dan Sullivan
  – Akifumi Hagiwara (Japan-QIBA)
  – Nandita deSouza (EIBALL)

QIBA AM Meeting Agenda

• Break and Start of Concurrent Biomarker Committee Sessions
  – CT  2nd Floor Conference Room
  – MR  3rd Floor Library
  – NM  4th Floor Conference Room
  – US  1st Floor Executive Conference Room
QIBA AM Meeting Agenda

- Coordinating Committee Updates
  - CT
  - MR
  - NM
  - US

- Panel Discussion 3: The Translation of QIBA Processes and Profiles into Clinical Trials
  - David Mozley, Moderator
QIBA AM Meeting Agenda

• QIBA Sustainability Implementation Group (SIG) Update
  – Prioritized Options for QIBA’s Evolution and Continued Accomplishment of Its Mission

QIBA AM Meeting Agenda

• Profile Conformance Process and Implementation Options
  – Kevin O’Donnell, Moderator
QIBA AM Meeting Agenda

• Process Committee Report and Discussion
  – Kevin O’Donnell, Chair – QIBA Process Committee