Welcome

- Since its formation in 2007, QIBA has benefited from the interests of >850 individuals from:
  - many interdisciplinary fields and responsibilities (radiology, imaging science, computer science, statistics, engineering, imaging equipment companies, software companies, pharma, imaging CROs, multiple federal agencies)
  - >150 companies, universities, and agencies
- Most of the efforts are voluntary
- Many groundwork projects supported in part or in whole by NIBIB contract funding
- All efforts enabled by the excellent staff at RSNA
- Thank you all!
Meeting Overview

Agenda, Wednesday, April 13

Morning
- Plenary Session 1: Krishna Kandarpa, MD, PhD / NIBIB
- Plenary Session 2: Gregory Farber, PhD / NIMH
- Establishing the Value of QI: Daniel Sullivan, MD
- Coordinating Committee Reports

Afternoon
- Process Committee Update: Profile Template & Stages
- Panel Discussion 1: Claim Guidance
- Panel Discussion 2: Profile Field / Feasibility Testing
- Biomarker Committee Breakout Sessions

Agenda, Thursday, April 14

Morning
- Panel Discussion 3: Conformance
- Report Out from Day-1 Breakout Sessions
- Collaborative Initiatives (International, ACR, etc.)
- QIDW Oversight Committee Report
- Process Committee Report and Discussion

Afternoon
- Biomarker Committee Breakout Sessions
Recent Activities

NIBIB Funding

- Completed 2\textsuperscript{nd} contract (Round 3 and Round 4 Groundwork Projects)
- Awarded 3\textsuperscript{rd} consecutive 2-year contract (2015-17)
- Summary of NIBIB-funded groundwork projects (~$625K per round):
  - Round 1 (2011-12): N=16 – complete
  - Round 2 (2012-13): N=12 – complete
  - Round 6 (2016-17): TBD

http://qibawiki.rsna.org/index.php?title=Main_Page => Claim and Profile Template Documents

Recent Activities

Continued Maturation of Policies and Procedures

- Improved consistency with respect to the content and structure of a QIBA Profile.
- Claim guidance and Profile template developed to address the continued evolution in statistical rigor.
Current Status

Profiles and Protocols

• **Completed (Publicly Reviewed):**
  • CT Tumor Volume Change Profile (v2.2)
  • FDG-PET/CT as an Imaging Biomarker for Measuring Response to Cancer Therapy Profile (v1.0)
  • DCE-MRI Quantification Profile (v1.0)
  • FDG-PET Protocol (with summary published in JNM in April 2015)

• **Nearing Release for Public Comment:**
  • DW-MRI
  • CT Small Nodule Volumetry
  • CT Lung Densitometry
  • PET Amyloid
  • fMRI
  • Ultrasound Shear Wave Speed

Profiles and Protocols (continued)

• **In Development:**
  • Revised CT Tumor Volume Change (liver)
  • Revised DCE-MRI (to address 3T and parallel imaging)
  • MR Diffusion Tensor Imaging (DTI)
  • MR Elastography
  • Dynamic Susceptibility Contrast (DSC)-MRI
  • MR Proton Density Fat Fraction (PDFF)
  • Ultrasound Volume Flow
  • SPECT
QIBA Metrology Working Group

• Five manuscripts published in *Statistical Methods for Medical Research* in 2014.
• One manuscript published in *Radiology* in 2015.

**QIBA Deliverables Based on Groundwork Projects with NIBIB and RSNA Support**

<table>
<thead>
<tr>
<th>Profiles* + Protocols</th>
<th>Manuscripts</th>
<th>Presentations</th>
<th>Posters</th>
<th>Physical Phantoms</th>
<th>DROs</th>
<th>Software Apps</th>
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As of April 8, 2016

*Publicly reviewed stage

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**Recent Activities**

**Evolution of Organizational Structure**

• Proliferation of committees and task forces suggested need for more uniform structure.

• Current organizational structure:
  • Steering Committee
    • Coordinating Committees (modality specific, N=4)
      • Biomarker Committees (N=11)
        • Task Force Groups (N=15)
  • Process Committee: Maintain QIBA policies and procedures; improve consistency between the expanding modality-specific biomarker profile developments
  • QIDW Oversight Committee: QIBA-specific Quantitative Imaging Data Warehouse issues
Challenges

- **Maintaining Momentum** => timely delivery of relevant work products
  - Realistic goals and well-defined, achievable criteria for success
    - Maintain focus on "industrializing QIBs" vs. academic desire for "perfecting QIBs"
    - Completion of existing efforts vs. initiation of new ones
    - Volunteer efforts bolstered by successes (as is sustainability of support)
  
- **Conformance Processes**
  - Availability of required phantoms, software, and data sets (w/meta data)
  - Well-defined test procedures (parameter space and pass criteria) => “check lists”

- **Field / Feasibility Testing of Profiles**
  - Establishing clear and realistic goal(s) of such tests to advance Profiles through the established stages
  - Identification of, and actively pursuing, opportunities for collaborations, e.g., cooperative group trials, international trials, etc.
Challenges

- **Sustainability**
  - Continued success in achieving well-defined, relevant goals => timely deliverables
  - Need to be critical to enabling adoption of QIBs (clinical trials, FDA, industry => patient care)
  - Conformance processes are a key component

- **QIDW**
  - Current uses confined to support of groundwork projects / profile drafting
  - Potential enabling role in conformance testing => need for well-defined procedures, data, software
    => determine future improvements and sources of support

- **Internationalization of QIBA**
  - Harmonization of efforts => creating opportunities for synergism

Opportunity

- **“Industrializing QIBs”**
  - Identifying sources of bias and variance in QIB measurements
  - Mitigating those sources to the degree possible
  - Defining confidence intervals => establishing true QIB measurands
  - Profile and Protocol development and promulgation

- **Implementation of QIB measurands, using QIBA Profiles, will enable:**
  - Optimal clinical trial designs, with appropriate sample sizes
  - Improved ability to combine QIB measurement results for statistically meaningful meta analyses
  - Radiomics / radiogenomics research
  - Objective data for decision support tools and evidence-based medicine
  - Delivery of precision medicine