QIBA Process Committee Call
Wednesday, May 31, 2017 at 3 PM CT
Call Summary

Attendees:			**RSNA Staff:**
Kevin O'Donnell, MASc (Chair)	Brian Garra, MD	Nancy Obuchowski, PhD	Joe Koudelik
Daniel Sullivan, MD (Co-Chair)	Edward Jackson, PhD	Eric Perlman, MD	Susan Weinmann
Michael Boss, PhD			

Profile Stages

- Meanings and criteria for the QIBA Profile Stages were discussed
- More clarity needed regarding Stage 3 and 4 wording, such as "confirm, number and kind of sites" needed for each stage
- Current information on QIBA Profile Stages can be found on the QIBA Wiki at: http://qibawiki.rsna.org/index.php/QIBA_Profile_Stages
- Recommendation to require a sample size of 35 patients as part of Stage 1: Consensus
- Stage 3: Technically Confirmed
    - The Profile has been found to be practical
    - Required sample size of patients to be determined
    - Statistical assumptions are valid
    - Profile is readable with practical procedures

- Stage 4: Claim-Confirmed
    - Alternative term for "Confirmed" needed; possibilities include, "Achieved" and "Demonstrated"
    - Systematic testing procedure required to assess overall performance
    - Conformance has been achieved
    - Guidance needed regarding number of scanner models to be tested
    - Data collection for Stage 4 less rigorous than Stage 5
    - To include a small trial or focused experiment
    - Biomarker measurements from at least two vendor systems and two sites meet all the Profile Claims

- Stage 5: Clinically-Confirmed
    - This stage still under discussion
    - Large study conducted using Profile
    - User is expected to reach performance if instructions followed
    - Conformance boundaries stressed regarding variability in Stage 5 using more challenging data
    - Profile used with multiple vendors, multiple sites, and significantly more than 35 patients

- Further clarification needed regarding differences between Stages 4 & 5 besides greater statistical "powering"
- FDG-PET investigating funding required for later Profile stages; discussion on simultaneous achievement of both Stages 4 & 5
- Stages to be labeled appropriately to convey a clear message
    - The way stages are currently written could infer that a Profile is successful only after reaching the final stage
    - May infer that a Profile is unsuccessful if it doesn't undergo all stages; in reality, Profiles can have an impact on users as early as Step 1: Consensus Stage, i.e., Profile development may be halted and "success" claimed at any stage
    - More information on how to use QIBA Profiles is located on the QIBA Wiki at: http://qibawiki.rsna.org/index.php/How_to_use_QIBA_Profiles

MR CC Voters

- The rationale behind setting the 15 voter maximum was to maintain a manageable group of core members and to increase likelihood quorum is reached
- All Biomarker Committee co-chairs are voting members of their respective modality Coordinating Committees
- Each Coordinating Committee may decide which CC members who are not BC Co-Chairs will be given voting privileges; they may choose to have fewer than 15 voters
- Because of the sheer number of Biomarker Committees within MR, the 15 voter maximum was exceeded by two after the addition of MSK BC co-chairs
- Process Cmte to propose to the Steering Committee that the voting member cap is increased from 15 to 20

Next Call: Wednesday, June 7, 2017 at 3 PM (Regular schedule to resume on June 28)