#### **QIBA Process Committee Call**

Tuesday, January 15, 2019 at 3 PM CT Call Summary

Attendees:

Kevin O'Donnell, MASc (Co-Chair)

Daniel Sullivan, MD (Co-Chair)

Edward Jackson, PhD

Nancy Obuchowski, PhD

Nicholas Petrick, PhD

Susan Stanfa

## QIBA Procedure Change Proposals (CP) Previously Approved by the Process Cmte

The following motions to be brought to the QIBA Steering Cmte (SC) for a vote during the January 17, 2019 meeting:

## CP-SC-001: Motion to be made to relax the voting privilege requirements

A member has voting privileges if, including the current meeting, they have attended two out of the last three four meetings.

# CP-SC-002 (Informational Item Only): Motion to be made for various modifications to committee procedures to clarify process and intentions

Meeting procedures, voting, email ballots, quorum, consensus procedures and committee leadership were addressed.

### CP-SC-003: Motion to be made to modify email ballot distribution

Eligible voting members will receive ballots and be encouraged to submit comments; non-eligible voting members will simply be notified of the ballot (but permitted to submit comments as well). Committee leaders have the discretion to accept or strike comments submitted by non-eligible voters.

## CP-SC-005: Motion to be made to not count "closed" QIBA meetings as member participation

"Open" meetings, such as t-cons and F2F meetings with remote access provided (t-con/WebEx) will count toward participation. "Closed" meetings, such as plenary or breakout sessions that are not open to all members and do not provide remote access (t-con), are not counted toward participation.

## QIBA Procedure Change Proposal (CP) Approved by the Process Cmte

The following meeting procedure update was discussed by the Process Cmte in preparation for consideration by the QIBA Steering Cmte (SC):

# CP-SC-004: Motion to be made to not count email ballots as member participation; voting privileges to be based on "open" meeting participation only.

- Consensus was reached that email ballots should be a separate category from t-con attendance and NOT count toward participation (no credit given for either returning a ballot or submitting feedback) for the following reasons:
  - This process of recording ballot returns in the attendance sheet was deemed overly complicated and time-consuming
  - Benefit of counting ballots toward participation deemed unclear or minimal; and the extra workload for data-keeping/tracking would be difficult to sustain

 Simplicity in processes is desired and gaining eligible voter status to cast ballots and provide feedback was deemed an incentive to attend t-cons, but there would be no need for any incentive to submit ballots and comments

**MOTION APPROVED:** Mr. O'Donnell moved, seconded by Dr. Jackson, to approve Change Proposal 4. Hearing no objections or abstentions, the motion was carried. This proposal will be brought to the next QIBA Steering Cmte call scheduled for Thursday, January 17, 2019.

## Review and Reprioritization of Current Work Items on Process CC Page of QIBA Wiki

Tasks were reviewed and reclassified under the following headings: "Current Work," "Priority" and "ToDo." These items can be found on the <u>Process Cmte page of the QIBA Wiki</u>.

#### **Current Work** (High Priority)

- QIBA BC leaders to be regularly reminded to keep QIBA Wiki BC page up-to-date (especially links to current draft documents)
  - A quick review of all BC wiki pages will be a standing agenda item for quarterly Coordinating Cmte meetings
  - o Mr. O'Donnell to draft some text as a standing item for all quarterly CC agendas

#### **Priority**

- Develop sunset procedure for retiring Task Forces and Biomarker Committees that have completed their work
  - Who proposes, considers, and decides to be determined (e.g., CC could make recommendation to SC or vice versa)
  - Status may be assigned to groups, such as active, dormant, or dissolved; terms to be better defined
  - In efforts to conserve resources, any new BC proposal to CC should trigger a review of current BC status; metrics needed for demonstrating productivity
- Review/update recommendations for new BC proposal review criteria
  - Upon the proposal of a new BC, existing BCs to be reviewed with consideration given to RSNA staff and funding resources to determine whether any could be reclassified as dormant or dissolved; this would be proposed as a mandatory action for adding a new BC
    - If a dormant group wishes to be reactivated, utilization of RSNA staff resources would need to be negotiated
  - Review/update new BC proposal review criteria
  - Recommendation that prior groundwork project completion will be a SC consideration when reviewing a new BC proposal from the same PI
    - A possible solution to a timing overlap of prior cycle completion period with a new BC proposal would be to require final reports for prior completed funding cycles before a new BC proposal would be considered

### **ToDo** (Low Priority)

#### Conformance Process

- Details to be documented within a conformance record are yet to be determined (e.g. findings from Technical Confirmation tests)
- Agreement needed regarding what conformance entails, how it is achieved, what it looks like for each product (i.e., for scanners and software), how it is documented, etc.
- Discussion needed on whether QIBA should host conformance statements on the website: they
  could be conveniently linked from the Profiles page, e.g., DICOM vendors post links to product
  conformance statements on their own websites
  - IHE created a product registry, hosted by RSNA, for vendors to log conformant product details
  - It was suggested was that RSNA staff could post an indexed list of QIBA-conformant products
  - Discussions regarding a conformant product list/database to be spearheaded by the Sustainability Implementation Group (SIG) as part of their Business Arm; the Process Cmte would simply keep track of this effort

#### Profile Template

- Profile Template (change tracked) to be adjusted to regroup time-muddled activities
- Poll to be created and sent to BC Profile editors to request feedback on the current template and suggestions for modifications
- Additional discussion needed on the clarity of the Conformance Section
- The Statistical Assumption Testing Guidance document was published
  - Suggestion for this paper to be incorporated into a clinical trials methodology course during the annual RSNA Clinical Trials Methodology Workshop (CTMW)
  - Conformance with the statistical assumptions is required at the various QIBA Profile stages

#### Clinical confirmation process

- Methodology/Study Design guidance/requirements for achieving "Clinically confirmed"
- Delineate specifics for Claim-Confirmed and Clinically-Confirmed stages
  - Discussion needed on whether it should be possible to skip Claim Confirmed and proceed directly to Clinically Confirmed

## QIBA Tools

- Access to Google Docs from governmental institutions (e.g., FDA) is not feasible due to security issues
- Google Doc FAQs and How-tos are available online: if questions/issues cannot be addressed through
  existing online materials, suggestion to develop Google Doc protocol geared toward QIBA Profile
  drafting and collaboration
- o Discussion needed regarding round trip fidelity between Word-Google-Word

- QIBA Wiki
  - Wiki page for public comments resolution spreadsheets to be created
  - o Currently, all referenced Profiles and working documents are located on the QIBA Wiki
    - Discussion on whether an intermediate site is needed
      - "Work" site (wiki) + "In Process" site (?) + "Polished" (website)
      - Mr. O'Donnell to work on specifics
      - Audience to be considered, as they may not always be radiologists
      - This would be an opportunity to formally reach beyond the Radiology field, e.g., to administrators and other clinical groups
    - Project proposal needed before entering the discussion phase regarding a new site
    - A new TF to push adoption beyond radiologists recommended; may include some Process
       Cmte members
  - o Whether "formal" documents should be on the Wiki vs. QIBA/RSNA Website was discussed
    - RSNA website is controlled by the RSNA Marketing Department, requiring resources beyond
       QIBA staff
- Literature Searches
  - Individuals with a draft set of guidance on best practices (Drs. Laue, Chung and Wu) to be invited to an upcoming Process Cmte call
- Mr. O'Donnell to reorganize "Current Work" list based on feedback during this call; prioritization review to be continued during an upcoming call

Next Call: Tuesday, February 5, 2019 at 3 PM CT (1st & 3rd Tuesdays)